



## **EPIDEMIOLOGY STUDY PROTOCOL**

**Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients  
Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics**

**Dronedarone**

**Study type:** Post Authorization safety Study

**Company:** Sanofi

**Version Number/Status:** Final v1

**Study number:** Drone\_C\_05917

**This study will be conducted in accordance with  
Sanofi standard operating procedures for GPE epidemiologic studies**

**Date:** 09-May-2017

**Total number of pages** 12 + (Appendices)

**PASS information:**

|                                               |                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Title:</b>                                 | Serious Liver Injury and Interstitial Lung Disease Occurrences in Patients Diagnosed with Atrial Fibrillation Treated with Selected Anti-arrhythmics                                                                                                                                                                                                                          |
| <b>Protocol version identifier</b>            | Final v1                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Date of last version of study report</b>   | N/A                                                                                                                                                                                                                                                                                                                                                                           |
| <b>EU PAS register number (if applicable)</b> | EUPAS18129                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Active substance</b>                       | Sanofi-aventis groupe<br>54 rue La Boétie<br>75008 Paris                                                                                                                                                                                                                                                                                                                      |
| <b>Medicinal product</b>                      | MULTAQ                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Product reference</b>                      | EU/1/09/591                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Procedure number</b>                       | EMA/H/C/001043                                                                                                                                                                                                                                                                                                                                                                |
| <b>Marketing authorization holder(s)</b>      | Sanofi-aventis groupe                                                                                                                                                                                                                                                                                                                                                         |
| <b>Joint PASS</b>                             | No                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Research questions and objective(s):</b>   | 1 - Compare rates of hospitalized serious liver injury/disease (SLD) in dronedarone-exposed patients compared to five separate anti-arrhythmic comparator cohorts all treated for AF<br><br>2 - Compare rates of hospitalized interstitial lung disease (ILD) in dronedarone-exposed patients compared to five separate anti-arrhythmic comparator cohorts all treated for AF |
| <b>Country(-ies) of study</b>                 | United States of America                                                                                                                                                                                                                                                                                                                                                      |
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*Appendix 1* – Study Report: DOD Database

*Appendix 2* – Study Report: HIRD Database

## 1 SUMMARY OF STUDIES

**Title:** Serious Liver Injury and Interstitial Lung Disease Occurrences in Patients Diagnosed with Atrial Fibrillation Treated with Selected Anti-Arrhythmics

## 2 RATIONALE AND BACKGROUND

Dronedarone (Multaq<sup>®</sup>) is an anti-arrhythmic drug with effects from all four classes of the Vaughan Williams classification indicated for treatment of patients with non-permanent Atrial Fibrillation (AF). Dronedarone was initially approved by the FDA on 1 July 2009 for marketing in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing analysis of spontaneous reports associated with dronedarone use identified safety signals related to *serious liver injury/disease* (SLD) and *interstitial lung disease* (ILD), which were also seen in association with the other anti-arrhythmics, notably amiodarone. In order to examine associations of dronedarone and comparator anti-arrhythmic drugs with these signaled events, Sanofi contracted with The Degge Group, Ltd. (Degge) to conduct a retrospective cohort study among adults in a real-world setting where dronedarone is approved for non-permanent AF.

## 3 RESEARCH QUESTION AND OBJECTIVES

The overall goals were to:

- Describe cohorts of patients treated for AF with dronedarone and comparator anti-arrhythmic drugs, and identify possible SLD and ILD outcomes in two different healthcare databases.
- Measure occurrences of SLD and ILD in cohorts of patients treated with dronedarone versus comparators treated with other anti-arrhythmic drugs.

Specific primary objectives were to:

- Compare rates of hospitalized **SLD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.
- Compare rates of hospitalized **ILD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.

## 4 STUDY DESIGN

Observational retrospective cohort study.

### 4.1 DATA SOURCES

The primary analysis for this study was conducted in the US Department of Defense, Military Health System Database (DoD) [Appendix 1](#). The Military Health System provides two types of care, direct care and purchased care, to its beneficiaries. Direct care is provided through a network of military hospitals and clinics, and purchased care is delivered by civilian providers financed through managed care contracts and fee-for-service reimbursements. Direct care accounts for 37% of all care provided. All administrative events generated by either a direct care or purchased care encounter are tracked in the central Military Health System Data Repository. The DoD database also includes records from the military's electronic medication ordering system called the Pharmacy Data Transaction System (PDTS). PDTS includes electronically coded dispensing details of both direct care and purchased care outpatient medication orders, including the prescribed drug name and National Drug Codes (NDCs), dose, quantity, refills and prescribing provider.

A parallel analysis was conducted in the HealthCore Integrated Research Database (HIRD) [Appendix 2](#). The HIRD<sup>SM</sup> is a broad, clinically rich and geographically diverse spectrum of longitudinal insurance claims data from plans in the Northeastern, Mid-Atlantic, Southeastern, Midwest, Central, and Western regions of the United States. It contains data on eligibility, medical, and pharmacy claims on more than 45 million members of one of the largest commercially insured populations in the United States. In addition, electronic laboratory results data are available for a subset of approximately 10 million patients. Outpatient medications are coded with NDCs as well as with Generic Product Indicators (GPI), which include the drug name, dosage form and drug strength.

### 4.2 STUDY PERIOD

The study period was 20 July 2008 to 30 September 2014.

### 4.3 SUBJECTS AND STUDY SIZE

*Overall patient inclusion criteria* for both studies were:

- 365 days of continuous eligibility in the health plan prior to and including the Index Date;
- A new prescription for any one of the following six anti-arrhythmic agents: **dronedarone**, **amiodarone**, **sotalol**, **flecainide**, **dofetilide**, or **propafenone**, dispensed between 20 July

2009 (the dronedarone launch date in the US) and 31 March 2014. The first of these drugs of interest dispensed during the patient selection period determined a patient's study cohort assignment and was referred to as the patient's Index Drug. The date on which that first study medication was dispensed was defined as the patient's Index Date, and the 365 days prior to and including the patient's Index Date defined their baseline period;

- Diagnosed with atrial fibrillation (AF, ICD-9-CM diagnosis code 427.31) during the baseline period;
- No use of the Index Drug during the baseline period. Use of non-index study drugs during the baseline period was allowed;
- Patient aged 18 years or older as of their Index Date.

*Overall patient exclusion criteria* for both studies were:

- Unknown gender;
- Index Drug use during the baseline period;
- Multiple study drugs on the Index Date;
- Less than 365 days of continuous eligibility in the health plan prior to and including the Index Date;
- Absence of a diagnosis of AF during the baseline period;
- A diagnosis of cancer, organ transplant, or HIV during the baseline period;
- Women who were pregnant during the 280 days prior to and including the Index Date, or became pregnant during the 280 days following the Index Date, or
- Date of death preceding Index Date.

*Outcome specific criteria* were applied to patients meeting the overall selection criteria to create separate SLD and ILD study populations. Patients included in the respective study populations could have no history of the relevant outcome of interest (i.e. SLD or ILD) during the 365 days prior to the Index Date. The SLD specific screening excluded patients with a history of the SLD outcome of interest, as well as patients with history of viral hepatitis, other related hepatitis or selected hereditary conditions (e.g. glycogenosis, alpha-1-antitrypsin deficiency). The ILD specific screening excluded patients with a history of the ILD outcome of interest and also excluded patients with history of pneumonia or sarcoidosis prior to their Index Date.

A total of 51,390 DoD patients met the general screening criteria. Following outcome specific screening 47,671 patients were retained in the DoD SLD study population, and 41,591 in the DoD ILD study population. There were 35,407 HIRD patients after general screening, and totals of 32,853 patients and 29,780 patients in the SLD and ILD study populations, respectively, after outcome specific screening.



DoD and HIRD outcome analyses were conducted in datasets generated from the corresponding study populations by using PS matching to minimize variability in baseline risk factors. As the numbers of patients in the dofetilide and propafenone drug groups did not meet the required sample size for the desired statistical power in either database, these two cohorts were eliminated from both the DoD and HIRD study populations prior to generating the PS-matched analysis datasets. SLD and ILD PS-matched analysis datasets for the DoD study contained 16,492 patients (4,123 per drug cohort) and 16,348 patients (4,087 per drug cohort), respectively. The HIRD analysis datasets contained totals of 11,084 SLD patients (2,771 per drug cohort) and 11,544 ILD patients (2,886 per drug cohort).

#### **4.4 STUDY VARIABLES**

Anonymized patient level records pertaining to patient demographics, inpatient and outpatient diagnoses and procedures, and pharmacy dispensing records were used to develop the measures used in the analyses.

#### **4.5 OUTCOME EVENTS**

Suspected SLD and ILD outcome events were defined as the first inpatient occurrence during the relevant risk period, in an acute care hospital or skilled nursing facility that had a discharge diagnosis or procedure code that met the outcome event definition. Suspected SLD outcome events were identified in the interval beginning the day after a patient's Index Date, and extending through the earliest occurrence of an SLD outcome, end of health plan eligibility, death or the end of days' supply of the last continuous prescription beginning with the Index Date. The risk period for identification of ILD events began the day after a patient's Index Date and extended to the earliest occurrence of an ILD outcome, end of health plan eligibility, death, or the end of the study.

Suspected outcome events in both the DoD and HIRD databases were adjudicated by two panels of three expert clinicians per panel (one panel for liver and one for pulmonary events). Each group of three panel members reviewed and adjudicated relevant profiles (SLD or ILD) for both DoD and HIRD databases. Adjudicators manually reviewed profiles consisting of up to one year of chronological patient history surrounding the suspected events, in order to determine whether the identified cases were valid outcome events. All patient records were de-identified, and panelists were blinded to patients' specific study drug exposures. Adjudicators separately reviewed each case and independently assigned a determination of "Yes," "No" or "Indeterminate" to the first inpatient occurrence of the outcome event. Unanimous assessments were considered as final decisions. When adjudicators differed in their initial determinations, formal meetings were held to review the cases. The chairperson facilitated the discussion where each adjudicator explained their initial determination. Adjudicators then indicated their final determination. The final decision for each suspected outcome event was based on a majority vote.

If each of the three adjudicators reached a different conclusion after discussion, then the case was considered “Indeterminate.”

## 5 ANALYTICAL APPROACH

Baseline risk factors relevant to each outcome were used to develop logistic regression models from which propensity scores (PS) were generated (predicting the probability of dronedarone exposure). Separate propensity scores were calculated for each outcome analysis (SLD, ILD). For each analysis, an attempt was made to find a PS-matched patient from each of the three comparator cohorts for each patient in the dronedarone cohort. PS matching was conducted using a nearest-neighbor-within-caliper matching algorithm, and was conducted without replacement. A qualifying matched case from each comparator cohort was required in order for a dronedarone case to be included in the analysis dataset.

Incidence rates of valid outcome events (cases adjudicated as “Yes”) were calculated per 1,000 person-years of exposure (SLD) or follow-up (ILD) stratified by study drug cohort. Graphs displaying separate Kaplan-Meier survival curves for each exposure group were also prepared, with one graph for each outcome event (i.e. SLD, ILD). The log-rank test was used to test the significance of differences between the dronedarone cohort and each comparator cohort.

Survival analysis for each outcome was carried out using separate Cox proportional-hazards regression models, with exposure group (dronedarone as the reference drug) as the main independent variable, and incorporating confounders that remained severely unbalanced after propensity score matching.

Due to ILD’s non-specific clinical presentations, which can include non-specific chest x-ray findings, as well as cough, a broad range of diagnoses may be assigned to ILD patients. In consideration of these complexities three sensitivity analyses, designed to determine any effect on the results from modifications of the definition of ILD and/or length of the risk period, were conducted in the DoD data to supplement the primary ILD analysis.

Two definitions of ILD were used for the analyses:

- The Narrow definition of ILD used a set of ICD-9-CM diagnosis codes described in a systematic review for the FDA’s Mini-Sentinel Project by Natalie Jones et al., 2012.
- The Broad definition of ILD expanded the Narrow definition by adding two diagnosis codes (495.9 Unspecified allergic alveolitis and pneumonitis, and 518.82 Other pulmonary insufficiency, not elsewhere classified).

Two risk periods were defined for the analyses:

- **ILD Risk Period 1** was the period that began the day after the Index Date and continued until the earliest occurrence of an ILD outcome, the end of MHS eligibility, death, or the end of follow-up.
- **ILD Risk Period 2** had a shorter maximum observation period. Beginning the day after the Index Date, **ILD Risk Period 2** ended at the earliest occurrence of an ILD outcome, the end of MHS eligibility, death, or the end of the index treatment episode.

## 6 RESULTS

Similar results were found in the cohort studies conducted in the two individual data sources.

Few suspected SLD cases were identified in either database (32 in the DoD database (see [Appendix 1](#)) and 16 in the HIRD database (see [Appendix 2](#)), and none received a “Yes” adjudication result. As no outcome events were confirmed as valid cases by the adjudicators, there were no differences in rates of SLD by study drug cohort in either analysis.

Of the 113 suspected cases of ILD identified in the DoD database, 52 were confirmed as “Yes” by the ILD adjudication panel. The amiodarone cohort was the only comparator group with a significantly different rate of ILD from that of dronedarone users. The amiodarone cohort had a significantly higher incidence rate of ILD with 2 cases per 1,000 person-years of follow-up, versus 0.8 cases per 1,000 person-years of follow-up in the dronedarone group. Amiodarone was associated with an adjusted hazard ratio for ILD of 2.5 (95% CI=1.1-5.3) relative to dronedarone over the course of the follow-up period. Results of the three ILD sensitivity analyses conducted in the DoD did not differ substantially from those of the primary ILD analysis conducted in that dataset.

In the HIRD study, 20 of the 33 suspected ILD cases were adjudicated as “Yes.” This equated to 1.3 cases per 1,000 person-years of follow-up among the HIRD dronedarone patients. ILD incidence rates in dronedarone users did not differ significantly from any other drug groups in the HIRD study, and none of the adjusted hazard ratios for ILD relative to dronedarone was significantly different from 1.

## 7 DISCUSSION

The granular longitudinal DoD and HIRD databases allowed extensive identification of pre-and post-exposure events in the selected cohorts, as well as propensity score matching to create analysis datasets that were balanced across study drug cohorts with respect to baseline risk factors. Suspected cases of SLD and ILD in the analysis datasets were carefully and

independently evaluated by specialty (hepatic and pulmonary) clinical adjudicators to determine the likelihood of being valid outcome events.

The SLD adjudicators determined that none of the 48 suspected cases of SLD found in the propensity score matched datasets was confirmed as SLD. Thus, there were no differences in rates of SLD between dronedarone and comparator drug users in either the DoD or HIRD data.

The ILD adjudicators confirmed 52 (46%) of the 113 cases of suspected ILD in the DoD study, and 20 (60.6%) of the 33 suspected cases in the HIRD study, as valid interstitial lung disease events. The difference in proportions of confirmed cases between the databases was not statistically significant ( $\chi^2=2.2$ ,  $p=0.14$ ). In the DoD study, the amiodarone cohort had 2.5 times the risk of a confirmed ILD event over the course of the follow-up period compared to the dronedarone cohort. There were no significant differences in rates of confirmed ILD events between the dronedarone patients and the patients treated with other anti-arrhythmics in the HIRD study.

In summary, these two retrospective cohort studies found no evidence of increased risk of SLD or ILD in AF patients treated with dronedarone versus patients using comparator drugs to treat AF.

## **APPENDICES**

## **APPENDIX 1      STUDY REPORT: DOD DATABASE**

## EPIDEMIOLOGY STUDY REPORT

### SERIOUS LIVER INJURY AND INTERSTITIAL LUNG DISEASE OCCURRENCES IN PATIENTS DIAGNOSED WITH ATRIAL FIBRILLATION TREATED WITH SELECTED ANTI-ARRHYTHMICS

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Study type: Post Authorization Safety Study  
Company: Sanofi  
Version Number/Status: Final v1  
Study Number: DRONE\_C\_05917

**This study was conducted in accordance with  
Sanofi standard operating procedures for epidemiologic studies**

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Date: 17-Mar-2017 Total number of pages: 803

**PASS information:**

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|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                                         | Serious Liver Injury and Interstitial Lung Disease Occurrences in Patients Diagnosed with Atrial Fibrillation Treated with Selected Anti-arrhythmics                                                                                                                                                                                                                                 |
| Version identifier of the final study report   | Final v1                                                                                                                                                                                                                                                                                                                                                                             |
| Date of last version of the final study report | N/A                                                                                                                                                                                                                                                                                                                                                                                  |
| EU PAS register number                         | EUPAS18129                                                                                                                                                                                                                                                                                                                                                                           |
| Active substance                               | Anti-arrhythmic drugs: dronedarone, amiodarone, sotalol, flecainide, dofetilide, propafenone                                                                                                                                                                                                                                                                                         |
| Medicinal product                              | MULTAQ                                                                                                                                                                                                                                                                                                                                                                               |
| Product reference                              | EU/1/09/591                                                                                                                                                                                                                                                                                                                                                                          |
| Procedure number                               | EMA/H/C/001043                                                                                                                                                                                                                                                                                                                                                                       |
| Marketing authorization holder(s)              | Sanofi-aventis groupe                                                                                                                                                                                                                                                                                                                                                                |
| Joint PASS                                     | No                                                                                                                                                                                                                                                                                                                                                                                   |
| Research questions and objective(s):           | <p>1 - Compare rates of hospitalized serious liver injury/disease (SLD) in dronedarone-exposed patients compared to five separate anti-arrhythmic comparator cohorts all treated for AF</p> <p>2 - Compare rates of hospitalized interstitial lung disease (ILD) in dronedarone-exposed patients compared to five separate anti-arrhythmic comparator cohorts all treated for AF</p> |
| Country(-ies) of study                         | United States of America                                                                                                                                                                                                                                                                                                                                                             |
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## ABBREVIATIONS

|                    |                                                                                           |
|--------------------|-------------------------------------------------------------------------------------------|
| ACE                | Angiotensin converting enzyme                                                             |
| AF                 | Atrial Fibrillation                                                                       |
| AFL                | Atrial flutter                                                                            |
| CHF                | Congestive heart failure                                                                  |
| CI                 | Confidence Interval                                                                       |
| COPD               | Chronic obstructive pulmonary disease                                                     |
| CPH                | Cox Proportional Hazard                                                                   |
| CPT <sup>®</sup>   | Current Procedural Terminology, American Medical Association                              |
| DCI                | Deyo-Charlson Index                                                                       |
| DEERS              | Defense Eligibility Enrollment Reporting System                                           |
| Degge              | The Degge Group, Ltd.                                                                     |
| DoD                | US Department of Defense, Military Health System Database                                 |
| DRG                | Diagnosis-Related Group                                                                   |
| EHR                | Electronic health record                                                                  |
| ESC                | Epidemiology Steering Committee                                                           |
| FDA                | US Food and Drug Administration                                                           |
| GERD               | Gastroesophageal Reflux Disease                                                           |
| HCPCS              | Healthcare Common Procedure Coding System, Centers for Medicare & Medicaid Services       |
| HIRD <sup>sm</sup> | HealthCore Integrated Research Database                                                   |
| HIV                | Human Immunodeficiency Virus                                                              |
| HR                 | Hazard Ratio                                                                              |
| HRTx               | Health ResearchTx, LLC                                                                    |
| IAC                | Independent Adjudication Committee                                                        |
| IAP                | Independent Adjudication Panel                                                            |
| ICD-9-CM           | International Classification of Diseases, 9 <sup>th</sup> Revision, Clinical Modification |
| ILD                | Interstitial lung disease                                                                 |
| MDR                | Military Health System Data Repository                                                    |
| MHS                | Military Health System                                                                    |
| NDC                | National Drug Code                                                                        |
| PDTS               | Pharmacy Data Transaction System                                                          |
| PS                 | Propensity Score                                                                          |
| PSM                | Propensity score matching                                                                 |
| SLD                | Serious liver injury/disease                                                              |

## 1. ABSTRACT

### Title

SERIOUS LIVER INJURY AND INTERSTITIAL LUNG DISEASE OCCURRENCES IN PATIENTS DIAGNOSED WITH ATRIAL FIBRILLATION TREATED WITH SELECTED ANTI-ARRHYTHMICS

### Keywords

Observational retrospective cohort study, dronedarone versus other anti-arrhythmics, serious liver diseases, interstitial lung disease

### Rationale and background

Dronedarone (Multaq<sup>®</sup>) is an anti-arrhythmic drug with effects from all four classes of the Vaughan Williams classification indicated for treatment of patients with non-permanent Atrial Fibrillation (AF).<sup>1</sup> Dronedarone was initially approved by FDA on 1 July 2009 for marketing in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing analysis of spontaneous reports associated with dronedarone use identified safety signals related to *serious liver injury/disease* (SLD), and *interstitial lung disease* (ILD), which are also seen in association with the other treatments, notably amiodarone.<sup>2</sup> In order to examine associations of dronedarone, and comparator anti-arrhythmic drugs, with these signaled events Sanofi contracted with The Degge Group, Ltd. (Degge) to conduct a retrospective cohort study among adults in a real-world setting where dronedarone is approved for non-permanent AF.

Treatment goals for AF include ventricular rate control, anticoagulation to prevent thromboembolism, and *elective* conversion to normal sinus rhythm and maintenance of sinus rhythm, depending on the clinical state of the patient.<sup>3</sup> Initial treatment involves either ventricular rate control or rhythm control. If ventricular rate control is the initial treatment strategy, rhythm control is not considered a therapeutic objective. On the other hand, if rhythm control is the initial treatment strategy, concomitant management of rate control is also addressed. Regardless of initial treatment strategy, antithrombotic therapy is considered. Patient response to the initial therapy guides further treatment decision-making.

Guidelines exist for the treatment of AF targeting rate and rhythm control (as well as anticoagulation) although some medications such as amiodarone used for treatment are not indicated for AF.<sup>4,5</sup> Rate control therapy consists of treatment with beta-blockers, calcium channel blockers, and digoxin, while amiodarone and other anti-arrhythmic agents are used for rhythm control.



## Research question and objectives

The overall goals were to:

- Describe cohorts of patients treated for AF with dronedarone and comparator drugs, and identify possible **SLD** and **ILD** outcomes in two different healthcare population databases.
- Measure occurrences of **SLD** and **ILD** in cohorts of patients treated with dronedarone versus comparators treated with other anti-arrhythmic drugs.

Specific primary objectives were to:

- Compare rates of hospitalized **SLD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.
- Compare rates of hospitalized **ILD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.

## Study design

Observational retrospective cohort study.

## Setting

US Department of Defense, Military Health System Database

## Subjects and study size

Patients were active participants in the Military Health System between 20 July 2008 and 30 September 2014. They were required to be  $\geq$  age 18 and have a first-time prescription for their anti-arrhythmic therapy for atrial fibrillation between 20 July 2009 and 31 March 2014 for inclusion in the study population. In addition, they were required to have at least 365 days of continuous enrollment prior to the index prescription fill, during which time a diagnosis of AF had to appear. Additional screening for the specific outcome study populations (SLD and ILD) were applied to remove patients who might have experienced the outcome prior to their Index Date.

A total of 47,671 patients were screened into the initial pool of patients for the SLD analysis. There were 41,591 patients screened into the pool of patients for the primary ILD analysis.

## Variables and data sources

Health ResearchTx (HRTx), a health research organization, has a unique partnership with the US Department of Defense to leverage the DoD MHS in order to improve health outcomes, lower costs, and increase force readiness. HRTx facilitated Degge's access to the DoD data through a secured server, using an encrypted login and password. HRTx obtained US Department of Defense Institutional Review Board approval required for this study, Protocol #NMCP.2014.0044.

Anonymized patient level records from the MHS data pertaining to patient demographics, hospital and outpatient diagnoses and procedures, and pharmacy dispensing records were used to develop the measures used in the analyses.

## Results

Results from this retrospective cohort study in two large electronic health record (EHR) population databases show that the incidence of SLD and ILD in patients with AF treated with dronedarone are not different than in patients using most comparator drugs. Few SLD cases were identified, and none were adjudicated as confirmed SLD. Less than 1 case of ILD per 1,000 person-years of exposure was estimated in dronedarone users. Amiodarone was associated with an adjusted risk of ILD 2.5 times higher than that of dronedarone, with a point estimate of 2 cases per 1,000 person-years of follow-up.

## Discussion

In these granular longitudinal datasets, the selected cohorts allowed extensive identification of pre- and post-exposure events, as well as propensity score matching to assure the cohorts were comparable as to baseline risk factors. The resulting possible cases of SLD and ILD were carefully and independently evaluated by specialty (hepatic and pulmonary) clinical adjudicators to determine the likelihood of being valid outcome events.

Adjudicators determined that none of the 32 suspected cases of SLD found in the propensity score matched dataset were confirmed SLD (though one was indeterminate). Thus, there were no differences in the rates of SLD between the propensity score matched cohorts.

There were 113 suspected cases of ILD in the corresponding propensity score matched dataset. Adjudicators confirmed 52 of those cases as interstitial lung disease events. Patients in the propensity score matched ILD population taking amiodarone had a 2.5 times higher risk than the dronedarone patients over the course of the follow-up period (95% CI:1.1-5.3) of a confirmed case of ILD.

Overall results from this retrospective cohort study show that the incidence of SLD and ILD in patients with AF treated with dronedarone are not different than in patients using comparator anti-arrhythmic drugs.

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- James H. Lewis, MD, *Hepatologist, Georgetown University, Washington, District of Columbia*
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## **Independent Adjudication Panels (IAP)**

### **IAP-SLD members included:**

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### **IAP-ILD members included:**

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## 4. MILESTONES

| <b>Milestone</b>                      | <b>Planned date</b> |
|---------------------------------------|---------------------|
| Start of study                        | 1 Oct 2014          |
| Study report – Draft version 1        | 14 Dec 2016         |
| Study report – Final version 1        | 3 Mar 2017          |
| <Registration in the EU PAS register> | 8 Mar 2017          |
| Final report of study results         | 20 Mar 2017         |

## 5. RATIONALE AND BACKGROUND

Dronedarone (Multaq<sup>®</sup>) is an anti-arrhythmic drug with effects from all four classes of the Vaughan Williams classification indicated for treatment of patients with non-permanent Atrial Fibrillation (AF).<sup>1\*</sup> Dronedarone was initially approved by FDA on 1 July 2009 for marketing in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing analysis of spontaneous reports associated with dronedarone use identified safety signals related to *serious liver injury/disease* (SLD), and *interstitial lung disease* (ILD), which are also seen in association with the other treatments, notably amiodarone.<sup>2</sup> In order to examine associations of dronedarone, and comparator anti-arrhythmic drugs, with these signaled events Sanofi contracted with The Degge Group, Ltd. (Degge) to conduct a retrospective cohort study among adults in a real-world setting where dronedarone is approved for non-permanent AF.

Treatment goals for AF include ventricular rate control, anticoagulation to prevent thromboembolism, and *elective* conversion to normal sinus rhythm and maintenance of sinus rhythm, depending on the clinical state of the patient.<sup>3</sup> Initial treatment involves either ventricular rate control or rhythm control. If ventricular rate control is the initial treatment strategy, rhythm control is not considered a therapeutic objective. On the other hand, if rhythm control is the initial treatment strategy, concomitant management of rate control is also addressed. Regardless of initial treatment strategy, antithrombotic therapy is considered. Patient response to the initial therapy guides further treatment decision-making.

Guidelines exist for the treatment of AF targeting rate and rhythm control (as well as anticoagulation) although some medications such as amiodarone used for treatment are not indicated for AF.<sup>4,5</sup> Rate control therapy consists of treatment with beta-blockers, calcium channel blockers, and digoxin, while amiodarone and other anti-arrhythmic agents are used for rhythm control.

---

\* Atrial flutter (AFL) was included as an indication on the dronedarone product label prior to December 2011. Approximately 0.6% of patients in both the Serious Liver Injury/Disease Study Cohort and the Interstitial Lung Disease Study Cohort had an AFL diagnosis only (data not shown). Given that small percentage, it was decided to exclude the AFL indication from this study.

## 6. RESEARCH QUESTIONS AND STUDY OBJECTIVES

The overall goals were to:

- Describe cohorts of patients treated for AF with dronedarone and comparator drugs, and identify possible **SLD** and **ILD** outcomes in two different healthcare population databases.
- Measure occurrences of **SLD** and **ILD** in cohorts of patients treated with dronedarone versus comparators treated with other anti-arrhythmic drugs.

Specific primary objectives were to:

- Compare rates of hospitalized **SLD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.
- Compare rates of hospitalized **ILD** in dronedarone-exposed patients to those of patients treated for AF with amiodarone, sotalol, flecainide, dofetilide, or propafenone.



## 7. AMENDMENTS AND UPDATES

| No. | Date     | Section of study protocol                                                   | Amendment or update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----|----------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Date     | Text                                                                        | Text                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2   | 5Oct2015 | SECTION 3.4<br>STUDY<br>POPULATION                                          | <ol style="list-style-type: none"> <li>Added Baseline Period definition</li> <li>Added sections describing outcome exclusionary screening criteria <ol style="list-style-type: none"> <li>For SLD – we will be excluding patient with a history of viral hepatitis and a history of hereditary conditions (See Appendix B.1) in the year prior to and including the Index Date.</li> <li>For ILD – we will be excluding patients with a history of pneumonia and a history of sarcoidosis (See Appendix C.1.1) in the year prior to and including the Index Date.</li> </ol> </li> <li>Revised Figure 1</li> </ol> |
|     |          | SECTION 3.5<br>TREATMENT<br>EPISODES AND<br>PATIENT<br>FOLLOW-UP<br>PERIODS | <ol style="list-style-type: none"> <li>Listed, separately, definitions for Treatment Episodes, Index Treatment Episodes, Switch Treatment Episodes, and Follow-up Periods</li> <li>Revised Figure 2</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                     |
|     |          | SECTION 3.6<br>OUTCOME<br>EVENTS OF<br>INTEREST                             | <ol style="list-style-type: none"> <li>Both outcome event descriptions and identifying outcome events for adjudication were edited</li> <li>ILD outcome event definition was revised – two definitions will be used: one narrow and one broad</li> </ol>                                                                                                                                                                                                                                                                                                                                                           |

| No. | Date | Section of study protocol                           | Amendment or update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----|------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |      | SECTION 3.7<br>ADJUDICATION<br>OF OUTCOME<br>EVENTS | <ol style="list-style-type: none"> <li>1. Panel member determination responses were revised to               <ol style="list-style-type: none"> <li>a. “Yes” – the patient profile contains diagnostic/procedural coding that meets the outcome event criteria</li> <li>b. “No” – the patient profile does not have diagnostic/procedural coding that meets the outcome event criteria, or</li> <li>c. “Indeterminate” – the patient profile does not have diagnostic/ procedural coding that meets the outcome event criteria, but the clinical picture suggests an outcome event may have occurred</li> </ol> </li> <li>2. Revised Figure 3 and Figure 4</li> </ol>                                                                                                                                                                                                                                  |
|     |      | SECTION 3.8<br>COVARIATES                           | <ol style="list-style-type: none"> <li>1. Reordered the SLD risk factors/ confounders               <ol style="list-style-type: none"> <li>a. Removed ‘Exposure to toxins through ingestion, inhalation, or skin absorption (e.g., toxic hepatitis)’ from SLD risk factors / confounders</li> <li>b. Added ‘Diabetes’ to SLD risk factors / confounders</li> </ol> </li> <li>2. Reordered the ILD risk factors/ confounders               <ol style="list-style-type: none"> <li>a. Removed History of Smoking as a risk factor – not reliably captured in the data</li> <li>b. Added Connective tissue disease</li> <li>c. Added Gastroesophageal reflux disease</li> <li>d. Added Agents associated with drug-induced pulmonary disease (antimicrobials, anti-inflammatories, biologics, cardiovascular agents, and chemotherapy agents)</li> <li>e. Added Interferon therapy</li> </ol> </li> </ol> |

| No. | Date | Section of study protocol                                | Amendment or update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----|------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |      | SECTION 4<br>STATISTICAL<br>ANALYSIS                     | <ol style="list-style-type: none"> <li>1. Moved the last paragraph from Section 3.5 to the first paragraph under Section 4.</li> <li>2. <b>“SECTION 4.2 OUTCOME EVENTS OF INTEREST REPORTING”</b> became <b>“SECTION 4.3 ANALYTIC APPROACH”</b> edited and revised to describe the overall descriptive summaries that will be generated</li> <li>3. <b>“Section 3.10 Controlling for Type-1 Errors”</b> was moved to Section 4.3.2</li> <li>4. SLD &amp; ILD sensitivity analyses were described separately in Sections 4.3.4.1 and Section 4.3.4.2, respectively</li> </ol> |
|     |      | SECTION 7 Tables and Figures                             | <p>Additional Report Tables were included for both Outcome Events as well as a sample Kaplan Meier Survival Curve:</p> <p>For SLD a table reporting on the Number of Index Treatment Episodes and Switch Episodes by Comparator Cohort, and a table reporting the PS Balancing Results of Covariates were added, as well as a sample Kaplan Meier Survival Curve.</p> <p>For ILD - two sets of ILD Tables will be generated: one set for ILD Narrow Definition (primary analysis), and one set for ILD Broad Definition (sensitivity analysis).</p>                          |
|     |      | Appendix A.1 – Study Drug Cohort Definitions             | <ol style="list-style-type: none"> <li>1. Additional NDC codes for study drug definitions were identified and added</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|     |      | Appendix A.2 – Other Medications of Interest was removed | <ol style="list-style-type: none"> <li>1. The medications were a carryover from a prior study, and had no bearing the SLD or the ILD outcome events</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                               |
|     |      | Appendix B.1                                             | <p>SLD Outcome Event Definition; Baseline Exclusionary Screening was inserted to show which conditions will be excluded for the SLD outcome event analysis. Appendices B.* numbering was revised for the remaining appendices.</p>                                                                                                                                                                                                                                                                                                                                           |

| No.      | Date             | Section of study protocol                                                         | Amendment or update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------|------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                  | Appendix C                                                                        | <p>Appendix was revised to account for two ILD outcome event definitions:</p> <p>ILD Narrow Definition:</p> <ul style="list-style-type: none"> <li>• Baseline Exclusionary Screening</li> <li>• Narrow Definition</li> <li>• Algorithm for Selection of Suspected ILD (Narrow) Outcome Events for Adjudication</li> </ul> <p>ILD Broad Definition:</p> <ul style="list-style-type: none"> <li>• Baseline Exclusionary Screening</li> <li>• Broad Definition</li> <li>• Algorithm for Selection of Suspected ILD (Broad) Outcome Events for Adjudication</li> </ul> |
|          |                  | Appendix D – SERIOUS LIVER INJURY/DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS | <p>Removed History of Viral Hepatitis, History of Hereditary Conditions from SLD risk factors section, added to the conditions being excluded in the baseline screening.</p> <p>Added codes to identify Diabetes and Obesity as risk factors; refined hepatotoxic medications list</p>                                                                                                                                                                                                                                                                             |
|          |                  | Appendix E - INTERSTITIAL LUNG DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS    | <p>Added codes for Connective Tissue Disease as a risk factor</p> <p>A sensitivity analysis will be conducted on “History of smoking” to assess the amount of data reported and whether or not it is feasible to analyze the data available.</p> <p>Removed History of Pneumonia and History of Sarcoidosis from ILD risk factors section, added to the conditions being excluded in the baseline screening.</p>                                                                                                                                                   |
| <b>3</b> | <b>15Jan2016</b> | Section 3.6, OUTCOME EVENTS OF INTEREST,                                          | <p>Outcome event - Hospitalization definition was revised to include skilled nursing facilities. New wording - “Hospitalizations will be restricted to inpatient stays in acute care hospital and skilled nursing facility settings only.”</p>                                                                                                                                                                                                                                                                                                                     |

| No. | Date | Section of study protocol                                                      | Amendment or update                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----|------|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |      | Section 3.6.2. INTERSTITIAL LUNG DISEASE (ILD)                                 | <ol style="list-style-type: none"> <li>1. Outcome event – Clarification of “hospital discharge diagnosis” was stated to refer to those diagnoses that appear on the facility record. Does not include diagnoses appearing on professional records.</li> <li>2. ILD definition revised to include any hospital discharge diagnosis, regardless if it is the primary discharge diagnosis or not.</li> <li>3. Exclusionary Conditions Definitions was inserted. This section was inserted to document the conditions being excluded during the patient selection process.</li> </ol> |
|     |      | Appendix D - LIVER INJURY/DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS      | The hepatotoxic medication list was updated.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|     |      | Appendix E - INTERSTITIAL LUNG DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS | The agents associated with pulmonary toxicity list was updated.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|     |      | Appendix F – PROPENSITY SCORE MODEL DEVELOPMENT: SELECTION OF VARIABLES        | Hepatology specialty (DoD only) was included along with Gastroenterology regarding specialty visits for SLD propensity score modeling.                                                                                                                                                                                                                                                                                                                                                                                                                                            |

## 8. RESEARCH METHODS

### 8.1 STUDY DESIGN

An observational retrospective cohort design was used to estimate rates of SLD and ILD occurring after treatment in dronedarone and comparator drug cohorts. Three sensitivity analyses were conducted for the ILD outcome, by alternately modifying the ILD definition and risk period.

An Epidemiology Steering Committee (ESC) monitored study progress. Two independent adjudication panels (IAPs), one for each outcome event, reviewed and adjudicated suspected outcome events. The ESC and two IAPs each had their own charter describing assigned roles and responsibilities. (See [Appendix 2.](#))

### 8.2 SETTING

Degge conducted the study, in collaboration with Sanofi, using data from the US Department of Defense Military Health System (MHS) database (DoD). A parallel study was conducted, under the supervision of Degge, in the HealthCore Integrated Research Database (HIRD<sup>SM</sup>). Findings from these studies provide insight into the risk of SLD and ILD in two different non-interventional, “real world” settings. The analyses conducted in the HIRD are provided in a separate report.

Prior to conducting the retrospective cohort studies, surveillance of the population exposed to dronedarone from the time of its approval (20 July 2009) was conducted in both databases in order to determine the feasibility of detecting, characterizing, and quantifying the occurrence of SLD and ILD outcome events associated with use of the drug. Degge coordinated both surveillance programs, which required:

1. Tracking, by quarter, the uptake of dronedarone and comparator drugs in the general population;
2. Developing definitions for suspected SLD and ILD outcome events;
3. Identifying suspected cases of SLD and ILD in patients with prescription dispensings for dronedarone and comparator drugs; and
4. Determining when sufficient numbers of users of dronedarone and comparator drugs were identified to conduct the requested epidemiological analysis.

See [Appendix 1](#) for a complete description of the dronedarone surveillance program.

## 8.2.1 United States Department of Defense, Military Health System Electronic Health Record System

The source population for this study included all beneficiaries in the MHS between 20 July 2008 and 30 September 2014. As a single payer system MHS provides uniform medical coverage and pharmacy benefits for more than 100 million covered lives, including both active duty and retired military members and their families (beneficiaries). Active duty members comprise approximately 17% of the MHS covered population.

DoD includes over 30 billion archived records, 5 billion online health records spanning more than 11 years, 20 years of ePrescribing and comparable decades of prescription, inpatient and outpatient data. Records of veterans who receive medical coverage through the Veterans Administration are not captured in the DoD database.

The MHS provides two types of care to its beneficiaries. *Direct care* is provided through a network of military hospitals and clinics, and *purchased care* is delivered by civilian providers financed through managed care contracts and fee-for-service reimbursements. Direct care accounts for 37% of all care provided. All administrative events generated by either a direct care or purchased care encounter are tracked in the central MHS Data Repository (MDR). Examples of data recorded in the MDR include patient demographic data, provider information (provider ID, specialty, and facility), diagnostic codes (ICD-9-CM codes for outpatient visits; Diagnosis-Related Group (DRG) codes for inpatient stays) and Current Procedural Terminology (CPT<sup>®</sup>) codes for procedures. Extensive patient information including address, age, race, rank, and active duty status is also stored within the MDR via connections with the Defense Eligibility Enrollment Reporting System (DEERS). DoD also includes records from the military's electronic medication ordering system called the Pharmacy Data Transaction System (PDTS). PDTS includes electronically coded dispensing details of both direct care and purchased care outpatient medication orders, including the prescribed drug name and National Drug Code (NDC), dose, quantity, refills and prescribing provider.

### Health ResearchTx, LLC / Department of Defense

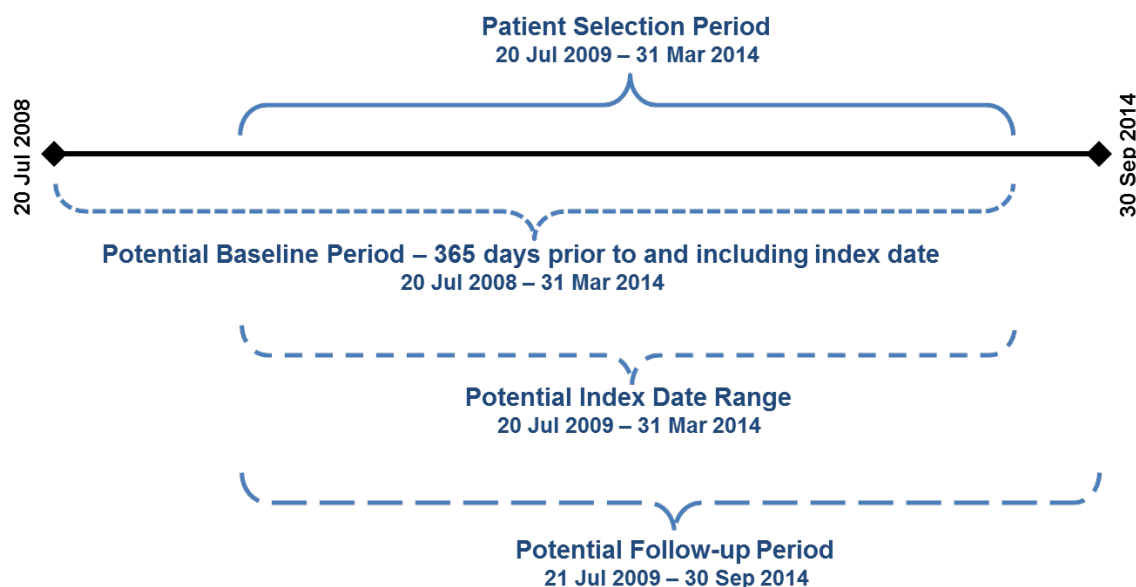
Health ResearchTx (HRTx), a health research organization, has a unique partnership with the US Department of Defense to leverage the DoD MHS system in order to improve health outcomes, lower costs, and increase force readiness. HRTx facilitated Degge's access to the DoD data through a secured server, using an encrypted login and password. HRTx obtained US Department of Defense Institutional Review Board approval required for this study, Protocol #NMCP.2014.0044.

## 8.3 SUBJECTS

### 8.3.1 Study Period

The study start date was 20 July 2008, and the study end date was 30 September 2014. Patients were selected for inclusion in the study drug cohorts on the basis of their drug dispensing records between 20 July 2009 and 31 March 2014. See [Figure 1](#).

**Figure 1. Patient Selection**



### 8.3.2 General Inclusion / Exclusion Criteria

The following criteria were used for the initial screening of patients for inclusion in the *Final study drug cohorts*.

#### 8.3.2.1 Inclusion Criteria

- 365 days of continuous eligibility in the MHS prior to and including the Index Date;
- A new prescription for any one of the following six anti-arrhythmic agents: **dronedarone**, **amiodarone**, **sotalol**, **flecainide**, **dofetilide**, or **propafenone**, dispensed between 20 July 2009 (the dronedarone launch date in the US) and 31 March 2014 (See [Appendix 3](#)). The first of these drugs of interest dispensed during the patient selection



period determined a patient's **study cohort** assignment and was referred to as the patient's Index Drug. The date on which that first study medication was dispensed was defined as the patient's Index Date, and the 365 days prior to and including the patient's Index Date defined their baseline period;

- Diagnosed with atrial fibrillation (AF, ICD-9-CM diagnosis code 427.31) during the baseline period\*;
- No use of the Index Drug during the baseline period. Use of non-index study drugs during the baseline period was allowed;
- Patient aged 18 years or older as of their Index Date.

#### **8.3.2.2 Exclusion Criteria**

- Unknown gender;
- Index Drug use during the baseline period;
- Multiple study drugs on the Index Date;
- Less than 365 days of continuous eligibility in the MHS prior to and including the Index Date;
- Absence of a diagnosis of AF during the baseline period;
- A diagnosis of cancer, organ transplant, or HIV during the baseline period (See [Appendix 4](#)).
- Women who were pregnant during the 280 days prior to and including the Index Date, or became pregnant during the 280 days following the Index Date [Appendix 4](#);
- Date of death preceding Index Date.

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\* Atrial flutter (AFL) was included as an indication on the dronedarone product label prior to December 2011. Approximately 0.6% of patients in both the Serious Liver Injury/Disease Study Cohort and the Interstitial Lung Disease Study Cohort had an AFL diagnosis only (data not shown). Given that small percentage, it was decided to exclude the AFL indication from the inclusion screening criteria of this study.

### 8.3.3 Outcome Specific Screening

Following the general screening, separate study drug cohorts were identified for each outcome of interest (Serious Liver Disease [SLD] and Interstitial Lung Disease [ILD]). Baseline records of patients in the *Final study drug cohorts* were screened to exclude those with pre-Index Date occurrences and/or related conditions relevant to the respective hepatic or pulmonary outcomes. The additional criteria were applied to better ensure that outcomes identified post-index would be truly incident events and not recurrences from the baseline period. Specific conditions for which each group of study cohorts were screened are described below.

#### 8.3.3.1 Serious Liver Injury Outcome (SLD) Cohort Screening

To create the *SLD study cohorts* – patients in the *Final study drug cohorts* with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) of the following conditions were excluded.

- History of Serious liver injury/disease;
- History of viral hepatitis; or
- History of hereditary conditions (e.g., Wilson’s disease, hemochromatosis, galactosemia, Alagille syndrome, alpha-1 antitrypsin deficiency, or type 1 glycogen storage disease).

(See [Appendix 5](#) for specific codes used to identify the conditions.)

Patients remaining after the SLD screening formed the *SLD study cohorts*.

#### 8.3.3.2 Interstitial Lung Disease Outcome (ILD) Cohort Screening

ILD may manifest itself within a few days or weeks after exposure, or take longer to appear (e.g., months or years). Furthermore, due to ILD’s non-specific clinical presentations, which can include non-specific chest x-ray findings, as well as cough, a broad range of diagnoses may be assigned to ILD patients. In consideration of these complexities, the primary ILD analysis was supplemented by three sensitivity analyses designed to determine any effect on the results from modification of the length of the risk period and/or ILD definition.

Given the planned sensitivity analyses, two definitions of ILD were used. The first was based on an established definition and is referred to as the ILD Narrow definition ([Section 8.4.4.2](#)). The second expanded the narrow definition with the addition of two diagnosis codes and is referred to as the ILD Broad definition ([Appendix 13](#)).

The *ILD Narrow definition study cohorts* were created by excluding patients in the *Final study drug cohorts* with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) of the following diseases:

- History of ILD Narrow definition;

- History of pneumonia; or
- History of sarcoidosis.

(See [Appendix 6](#) for specific codes used to identify the conditions):

Patients remaining after the ILD Narrow definition screening formed the *ILD Narrow definition study cohorts*, which was used for the primary ILD analysis.

## 8.4 VARIABLES

### 8.4.1 Treatment Episode

A *treatment episode* was defined as a continuous period starting on the date a study drug was dispensed, and continuing for the duration of the last refill's days' supply. In cases where there was a gap of fewer than 30 days between the date on which a days' supply ended and the dispensing date of a subsequent refill for the same drug, the subsequent refill was considered a continuation of the first treatment episode.

A **treatment episode** ended on the date when the days' supply for the last refill in the episode was calculated to run out, plus 30 days (added as a risk window to account for potential non-compliance or missed doses). In cases where a different study drug was dispensed (treatment switch) prior to the end of a treatment episode (i.e., a treatment episode for the new drug begins), the end date of the first episode was changed to the day preceding the start of the treatment switch. A treatment episode end date was also changed to the earliest of the date of death, end of MHS eligibility or end of study, should any of those events have occurred prior to the calculated end of a treatment episode.

The **index treatment episode** was defined as the treatment episode that began on a patient's Index Date. See [Appendix 7 - Figure 1](#).

### 8.4.2 Follow-up Period

The **follow-up period** references the amount of time after their Index Date for which records were available for each patient. The **follow-up period** started the day after the Index Date and ended at the first occurrence of either the end of the study period, end of MHS eligibility, or death.

### 8.4.3 Risk Period

The **risk period** was the interval of time for which patient records were examined to identify suspected outcomes. The sensitivity analyses conducted for the ILD outcome involved identification of ILD outcomes in two different Risk Periods, which will be referred to as *ILD risk Period 1* and *ILD risk period 2*. The *SLD risk period* and *ILD risk period 1* (used for the ILD primary analysis) are defined below. *ILD risk period 2* is defined in [Appendix 7](#), which reports on the ILD sensitivity analyses.

***SLD risk period*** was defined as the period beginning the day after the Index Date and continuing until the earliest occurrence of an SLD outcome, end of MHS eligibility, death, or the end of the index treatment episode. See [Appendix 7 - Figure 1](#).

***ILD risk period 1*** was defined as the period that began the day after the Index Date and continued until the earliest occurrence of an ILD outcome, the end of MHS eligibility, death, or the end of follow-up. See [Appendix 7 - Figure 2](#).

***ILD risk period 2*** was defined as the period that began the day after the Index Date and continued until the earliest occurrence of an ILD outcome, end of MHS eligibility, death, or the end of the index treatment episode.

### 8.4.4 Outcome Events of Interest

Outcome events of interest for the primary analyses were incident cases associated with a hospitalization (and not a related outpatient code) for:

- Serious liver injury/disease during the *SLD risk period*;
- Interstitial lung disease, defined by the ILD Narrow Definition, during *ILD risk period 1*.

As each outcome event was analyzed separately, an occurrence of one outcome of interest did not censor follow up for the other (e.g., an SLD occurrence did not preclude following an eligible patient for a subsequent occurrence of ILD). Only the first hospitalized outcome event occurrence was assessed in each of the respective outcome event analyses. In the context of this study, a hospitalization was defined as an inpatient stay at an acute care hospital or skilled nursing facility.

#### 8.4.4.1 Serious Liver Injury/Disease (SLD) Outcome Event Definition

Suspected SLD outcome events were identified by inpatient ICD-9-CM diagnosis / procedure codes or CPT<sup>®</sup> procedure codes (see [Appendix 8](#)). Two groups of codes, referred to as **Group A Codes** and **Group B Codes** were used to identify SLD outcome events. In all cases the first occurrence of one of the codes was required to appear among the facility record discharge

diagnoses, and the admission date of the hospitalization with the SLD defining code must have fallen within the *SLD risk period*.

The codes used to define the SLD outcome event (Group A and Group B) originated with a group of definitions previously validated for the Mini-Sentinel Project by V. Lo Re et al.<sup>6</sup> and another set developed by K Arnold Chan et al.<sup>7</sup> The initial list developed from those two sources were reviewed and modified by the ESC and SDL adjudication panel.

**Group A Codes** ([Appendix 8](#)) were considered to usually reflect liver injury / disease and were not required to be a primary discharge diagnosis. Patients were selected for adjudication review if the first occurrence of any of the following codes appeared anywhere among the facility record discharge diagnoses:

**ICD-9-CM Diagnosis Codes**

570 Acute and subacute necrosis of liver  
 572.2 Hepatic coma  
 572.4 Hepatorenal syndrome  
 V42.7 Liver replaced by transplant

**ICD-9-CM Procedures Codes**

50.5 Liver transplant  
 50.51 Auxiliary liver transplant  
 50.59 Other transplant of liver

**CPT® Procedure Codes**

47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole

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**Group B Codes** ([Appendix 8](#)) were considered highly suspicious indicators of SLD and were required to be a primary facility discharge diagnosis. Patients were selected for adjudication review if the first occurrence of any of the following codes appeared as a primary discharge diagnosis on the facility record:

**ICD-9-CM Diagnosis Codes**

277.4 Disorders of bilirubin excretion  
 571.5 Cirrhosis of liver without mention of alcohol  
 572.8 Other sequelae of chronic liver disease  
 573.0 Chronic passive congestion of liver  
 573.3 Hepatitis, unspecified  
 573.8 Other specified disorders of liver  
 573.9 Unspecified disorder of liver

782.4 Jaundice, unspecified  
 794.8 Non-specific abnormal results of liver function test

#### **ICD-9-CM Procedure Codes**

50.11 Closed (percutaneous) [needle] biopsy of liver  
 50.12 Open biopsy of liver  
 50.13 Transjugular liver biopsy  
 50.14 Laparoscopic liver biopsy  
 50.91 Percutaneous aspiration of liver

#### **CPT® Procedure Codes**

47000 Biopsy of liver, needle; percutaneous  
 47001 Biopsy of liver, needle; done at time of other major procedure  
 47100 Biopsy of liver, wedge  
 78205 Liver imaging (SPECT)  
 78206 Liver imaging (SPECT); with vascular flow

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**Appendix 8** provides a flowchart that illustrates the algorithm employed to select patients for SLD adjudication review.

#### **8.4.4.2 Interstitial Lung Disease (ILD) Outcome Event Definition**

Suspected outcomes for the ILD primary analysis were identified using the ILD Narrow definition. The ILD Narrow definition (**Appendix 9**) was based on inpatient ICD-9-CM diagnosis codes described in a systematic review for the FDA's Mini-Sentinel Project by Natalie Jones et al.<sup>8</sup>

For each patient, the first hospitalization with a discharge diagnosis code meeting the ILD Narrow definition within *ILD risk period 1* was identified as the suspect ILD outcome event. The ILD defining diagnosis code could appear anywhere among the facility discharge diagnoses (i.e., it did not have to be the primary discharge diagnosis). The admission date of the hospitalization with the ILD defining code was assigned as the suspect ILD outcome event date.

The ILD Narrow definition outcome codes were:

#### **ILD Narrow Definition - ICD-9-CM Diagnosis Codes**

515 Post-inflammatory pulmonary fibrosis  
 516.3 Idiopathic fibrosing alveolitis  
     516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)  
     516.31 Idiopathic pulmonary fibrosis (IPF)  
     516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)  
     516.33 Acute interstitial pneumonitis (AIP)

|        |                                                              |
|--------|--------------------------------------------------------------|
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD) |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)             |
| 516.36 | Cryptogenic organizing pneumonia (COP)                       |
| 516.37 | Desquamative interstitial pneumonia (DIP)                    |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy       |

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Please note that there is limited literature providing administrative and claims data-based definitions / coding algorithms to identify ILD. Although none of the ICD-9-CM codes listed above have been validated, and they may not provide optimum levels of sensitivity and specificity, they were reviewed and approved for use in this study by the Epidemiology Steering Committee and, subsequently, the ILD Adjudication Committee.

[Appendix 9](#) illustrates the process used to select patients during ILD Risk Period 1 based on the ILD Narrow Definition for adjudication review.

## 8.5 IDENTIFICATION OF POSSIBLE CONFOUNDERS/RISK FACTORS

A confounder is a variable that is related to both the exposure and the outcome event of interest. The following variables were identified as potential confounders in the DoD data analysis.

### 8.5.1 SLD Potential Risk Factors / Confounders

- History of Alcoholism;
- History of Bile duct disorders;
- History of Congestive heart failure;
- History of Diabetes;
- History of Obesity;
- Use of other anti-arrhythmic medications (non-study medications);
- Prior use of potentially hepatotoxic medications (systemic use only).

See [Appendix 10](#) for code list definitions.<sup>9</sup>

### 8.5.2 ILD Potential Risk Factors / Confounders

- History of Asthma;
- History of Bronchitis, excluding acute bronchitis;
- History of Chronic obstructive pulmonary disease;
- History of Connective tissue disease;
- History of Exposure to occupational and environmental toxins;
- History of Gastroesophageal reflux disease;
- Use of other anti-arrhythmic medications (non-study medications)

- Prior use of agents associated with drug-induced pulmonary disease, (systemic use only)<sup>10</sup>;
- Prior use of Therapeutic oxygen treatment.

See [Appendix 11](#) for code list definitions.<sup>11</sup>

## 8.6 ADJUDICATION OF OUTCOME EVENTS

Outcome event adjudication involved manual review of patients' medical and prescription histories from the electronic medical records (DOD) and medical claims data (HIRD). Patient histories surrounding the suspected event(s) for patients with occurrences of one or both outcome events (SLD or ILD) were reviewed by the respective IAP. If available, up to one year of patient history preceding the Index Date, and up to six months of history following the outcome event was provided for suspected SLD cases. For suspected ILD events, history up to one year preceding the Index Date and through the end of the patient's follow-up period was provided for IAP review. The data were formatted as patient profiles, with all diagnoses, procedures, drug dispensings, and other available data presented chronologically for IAP members' review.

In order to blind IAP members to all patient-identifying information, profiles were codified with encrypted patient numbers. Dispensing records involving study drugs were *highlighted* in the patient profiles, although IAP members were blinded to the specific study drug exposure (drug name, quantity, and formulation), the dispensing date and the quantity dispensed were provided. Members of the appropriate IAP reviewed each case independently and determined, given the patient records and timing of the outcome event relative to patient's ongoing medical and drug history, whether the suspected outcome event was likely a valid outcome event or confounded by other medical conditions occurring at the same time.

Each IAP member indicated their determination from the list below for each suspected outcome:

- **“Yes”** – the patient profile contains diagnostic/procedural coding that meets the outcome event criteria.
- **“No”** – the patient profile does not have diagnostic/procedural coding that meets the outcome event criteria.
- **“Indeterminate”** – the patient profile does not have diagnostic/ procedural coding that meets the outcome event criteria, but the clinical picture suggests an outcome event may have occurred.

Panel member decisions were tabulated for each outcome event. In cases where panel members' decisions were unanimous, the agreed upon determination was entered for the case in the study database. No further discussion was needed. When panel members disagreed regarding an outcome determination, the patient profile was discussed in a formal meeting where all three IAP



members and the Chair were present. The Chair led the discussion. After each panel member presented and discussed the reasoning for their decision, a final vote was taken. If the final vote was unanimous, or reflected a majority decision (i.e., 2 of the same decision), that decision was assigned to the outcome event in the study database. If each of the three IAP members reached a different conclusion, the outcome event was assigned the value “Indeterminate” in the study database.

## 8.7 BIAS

### Propensity Score Matching

In order to account in the analyses for baseline patient characteristics that are known measureable confounders, propensity score (PS) matching was used to balance those characteristics as much as possible for the final outcomes analyses. Separate propensity score matching was conducted for the SLD, *ILD Narrow definition* and *ILD Broad definition* populations. (See [Section 8.10.2.1](#))

All outcomes analyses were conducted in the PS-matched analysis datasets.

## 8.8 STUDY SIZE

Sample-size requirements for the analyses were estimated based on the following statistical design parameters and assumptions. They are based on the population size prior to propensity score matching.

- **Type of Analysis:** Comparison of event-free “survival” time between the dronedarone-exposed cohort and each comparator (reference) cohort, by means of the log-rank test, or Cox proportional-hazards regression
- **Alpha Level:** 0.05 ( $p \leq 0.05$  considered statistically significant)
- **Power:** 80% (80% chance of obtaining a significant result if a true difference in event-free survival between cohorts exists, and is of an important magnitude)
- **Effect Size of Importance:** Hazard Ratio = 3.0
- **Incidence Rate in the Comparator (Reference) Group:** 1 event/1,000 patient-years
- **Group size Ratio:** 1:1 (equal numbers of dronedarone and comparator subjects), consistent with 1:1 propensity-score matching
- **Accrual Interval:** 5 years (July 2009 through March 2014)
- **Follow-up Beyond Last Accrual:** 6 months (Index Dates ranged from July 2009 through March 2014)

The following chart shows the number of dronedarone subjects required to provide 80% power, at the 0.05 alpha level, to detect hazard ratios of 2.0, 3.0, and 4.0, for various values of the comparator (reference) group incidence rate:

| Incidence Rate (Events / patient-years<br>In the Comparator Group) | # of Subjects Needed<br>in Each Cohort |              |        |
|--------------------------------------------------------------------|----------------------------------------|--------------|--------|
|                                                                    | HR=2.0                                 | HR=3.0       | HR=4.0 |
| 0.01%/year (1 / 10,000 patient-years)                              | 108,947                                | 38,553       | 22,698 |
| 0.02%/year (1 / 5,000 patient-years)                               | 54,477                                 | 19,278       | 11,351 |
| 0.05%/year (1 / 2,000 patient-years)                               | 21,800                                 | 7,714        | 4,542  |
| 0.1%/year (1 / 1,000 patient-years)                                | 10,906                                 | <b>3,860</b> | 2,273  |
| 0.2%/year (1 / 500 patient-years)                                  | 5,460                                  | 1,933        | 1,138  |
| 0.5%/year (1 / 200 patient-years)                                  | 2,192                                  | 776          | 457    |
| 1%/year (1 / 100 patient-years)                                    | 1,103                                  | 391          | 231    |

[Software used to produce calculations: PS - Power and Sample Size Calculations, version 3.0, by W. D. Dupont and W. D. Plummer (Vanderbilt University).]

The incidence rate of 1 per 1,000 patient years was considered a sufficiently conservative estimate to use in the sample size calculations. Therefore, for a hazard ratio (HR) of 3.0, the minimum required sample size was 3,860 patients per study drug cohort.

The *dofetilide* and *propafenone* cohorts did not meet the required sample size of 3,860 patients. They were excluded prior to the propensity score matched process.

Background data to support the sample size and power calculations were provided by Sanofi from a retrospective cohort study conducted internally by the company in 2011. That study used integrated medical and prescription claims data from the LabRx database (Safety Study Report – Dronedarone, SR33589, GPE Pharmacoepidemiology, August 2, 2011). That study found the following:

| Outcome Studied                              | Incidence Rate in dronedarone cohort / 1,000 PYs |
|----------------------------------------------|--------------------------------------------------|
| Incidence of acute liver injury <sup>‡</sup> | 7.6 (0.9 - 14.2)                                 |
| Incidence of interstitial lung disease       | 21.9 (10.5 - 33.4)                               |

<sup>‡</sup> Defined as a primary diagnosis of acute or sub-acute necrosis of liver, hepatic coma, toxic hepatitis, or liver transplant in hospital by ICD-9-CM and CPT codes.

## 8.9 DATA MANAGEMENT AND TRANSFORMATION

An extract of the DoD data meeting requirements specified for the study was provided by HRTx. The de-identified data were made available to Degge as SAS datasets, accessible remotely on a secure site administered by Evolvent / ManTech International Corporation (Evolvent). Degge staff applied screening criteria to identify cases meeting eligibility requirements for the analyses, generated summary baseline variables and identified relevant outcomes to create analysis datasets on the Evolvent site using SAS 9.2 (Cary, NC). The analysis datasets were accessed by Degge's end users where descriptive tables were produced and analyses conducted using SAS 9.4 (Cary, NC).

## 8.10 STATISTICAL METHODS

### 8.10.1 Main summary measures

Selected baseline and post-Index Date characteristics are summarized in tabular format for patients in each outcome study population prior to PS matching, as well as for patients in the respective propensity score matched analysis datasets. General categories of reported characteristics include demographics (age, gender and race), baseline history of diseases relevant to each outcome of interest, and baseline use of medications relevant to each outcome of interest.

In addition to baseline characteristics, patient follow-up time, length of index treatment episode, and number of non-index study drugs dispensed after the Index Date are summarized for all pre- and post-PS-matched datasets.

Summary descriptive data are reported as either mean values (e.g., Deyo-Charlson Index) or proportions (e.g., distribution by race).

Data were also tabulated to show person-years of exposure and number of events during the relevant risk period, by cohort, for each outcome (i.e., SLD and ILD). Incidence rates per 1,000 person-years of exposure (SLD) or follow-up (ILD) and accompanying 95% confidence intervals (CI) were then calculated for each outcome. The log-rank (Mantel-Haenszel) test was used to test the significance of differences in incidence rates between the dronedarone cohort and each comparator cohort. Cox Proportional Hazards (CPH) modeling was conducted to compare event rates over time, between cohorts, with dronedarone as the referent study drug. The HR, 95% CI and p-value of the results are presented for each analysis.

### 8.10.2 Main statistical methods

#### 8.10.2.1 Propensity Score Matching

Dronedarone is the newest of the anti-arrhythmics considered in this study, and there are likely factors that influenced physicians' decisions to initiate treatment with this drug (as well as decisions to treat with the other study drugs). In order to account in the analyses for potential patient characteristics that are known measurable confounders (i.e., they may influence the decision to initiate treatment on a particular drug, and also affect patient outcomes) PS matching was used to balance, as much as possible, those baseline characteristics. Separate PS matching was conducted for the SLD, *ILD Narrow definition* and *ILD Broad definition* populations. Patients in each of the three comparator cohorts meeting the size requirement (i.e., amiodarone, sotalol and flecainide) were PS matched to patients in the dronedarone cohort. The PS matching process is described below in more detail.

#### **8.10.2.2 Propensity Score Matching Procedure**

Propensity score matching (PSM) is a statistical technique that attempts to isolate the estimated effect of a treatment or exposure by accounting for the covariates that predict the likelihood of the exposure. PSM employs a predicted probability of exposure based on observed predictors, usually obtained from logistic regression. The technique provides a close adjustment for differences in covariates at baseline and thereby reduces bias due to confounding variables that could be found in an estimate of the exposure effect obtained from simply comparing outcomes among exposed subjects (in this case, the dronedarone cohort) versus unexposed subjects (the comparator cohorts).

An attempt was made to match one patient from each of the three comparator cohorts amiodarone, sotalol, and flecainide to each patient in the dronedarone cohort according to PS. The matching was conducted without replacement. Specifically, three separate subsets of the DoD database, each containing all of the dronedarone patients and patients from one of the comparator cohorts were created. The same reduced logistic regression model (derived from the dataset combining all cohorts) was independently fitted to each of the subsets and the results used to calculate a PS for each patient in the subset. Within each subset, the absolute difference between PS scores for each dronedarone and comparator patient was calculated. Selecting dronedarone patients in random order, and employing a caliper of 0.2 (i.e., the maximum allowable difference between treatment and control PS scores was 0.2 X the standard deviation of the mean propensity score for data comprised of the dronedarone patients plus the comparator cohort being matched), the closest patient in each comparator cohort was selected for matching (from remaining comparators not already matched to another dronedarone patient). If matches for a given dronedarone subject were not found across all comparator groups then the dronedarone subject was considered unmatchable and excluded from the analysis. (See

**Appendix 12 – Figure 1)**

PS matching generated a dataset of patients whose baseline covariate distributions were nearly identical across the four cohorts. This allowed for comparison of outcomes between dronedarone users and comparator cohorts using transparent, simpler unmatched methods that do not require explicit adjustments for individual confounders. Multiple variations of PS models and matching schema were tested in order to find the best match of baseline characteristics. In the event that one or more variables remained severely unbalanced between the amiodarone cohort and one or more of the PS-matched comparator groups after PS matching (see section 8.10.2.6), an explicit adjustment for the severely unbalanced confounder(s) was included as a covariate in the relevant CPH model.

#### **8.10.2.3 Evaluation of Propensity Score Model and Matching**

The adequacy of PS-based matching was assessed in several ways:

- The goodness of fit of the logistic model was examined using the Lemeshow<sup>12</sup> test for calibration and by the C-statistic for discrimination.
- The choice of caliper width was justified by sensitivity analysis of a range of caliper widths, demonstrating that the chosen width (0.2) strikes an acceptable balance between number of potential matches and closeness of the match (described below).
- Standardized differences were used to compare baseline values of the potential confounders between the PS-matched dronedarone cohort and each of the PS-matched comparator cohorts to ensure balance across the cohorts.
- Survival analyses were conducted for groups stratified by PS-quintile, and also by including PS as a covariate in the Cox proportional hazards regression analyses. These sensitivity analyses ruled out any potential systematic differences in results by PS score.

#### **8.10.2.4 Fit of the Logistic Model**

The adequacy of the logistic model to represent the dependence of dronedarone exposure on the baseline values of the available potential confounders was checked in several ways.

- The fit was evaluated graphically. All records were sorted by PS and a graph was generated of the cumulative sum of the PS values (y), versus the corresponding cumulative fraction of subjects who were actually in the exposed category (x). If the data actually conformed to the fitted logistic model, the plotted points would lie exactly along a straight diagonal line between (0,0) and (1,1).
- The adequacy of the logistic fit was also evaluated by the Lemeshow test for calibration and by the C statistic for discrimination.

#### **8.10.2.5 Effect of Caliper Width**

The log-odds of the probability calculated by the reduced logistic regression model was used as the PS. (The log-odds is the linear portion of the logistic model, prior to transformation into a probability.) Caliper width for nearest-neighbor matching was based on a fraction of the standard deviation of the PS. Several caliper-width strategies were evaluated, and a choice made so as to achieve an acceptable tradeoff between poor matching (caliper too wide) and excessive exclusion of patients from the matched population (caliper too narrow).

#### **8.10.2.6 Balance of Baseline Values between Matched Cohorts**

Tables summarizing baseline measures of potential confounders for patients in each of the cohorts retained for the analyses were generated both before and after PS matching (means and standard deviations for continuous variables; numbers and proportions for dichotomous variables). Standardized differences were calculated to compare the balance of baseline confounder values between the dronedarone patients and patients in each comparator cohort. Confounders were considered well balanced if the value of the standardized difference was 10% or less. Confounders with standardized differences >25% were considered severely unbalanced.

#### **8.10.2.7 Variability of Hazard Ratios with PS for the Primary Outcome**

Unlike randomization, which (in the long run) will compensate for the effects of all known and unknown confounders between groups, PS matching can hope to compensate only for known confounders that were included in the PS model. Therefore, even in a study where PS matching has been executed perfectly, and the cohorts are completely balanced for all known confounders, the outcome event can be affected by unknown confounders that remain unbalanced between cohorts. This is an intrinsic limitation of PS matching. It has been tested for in two ways:

- Running analyses for groups of patients stratified by PS-based quintiles, and checking whether the outcomes vary systematically across the sequenced strata.
- Incorporating the PS as a covariate (with interaction terms between PS and the cohorts), and checking whether the coefficients of the interaction terms are significantly different from zero.

If PS-dependence of outcomes were observed, it would mean that the effect of a comparator drug on the outcome, relative to dronedarone, could be biased by the unknown (and uncompensated) confounders. Results would therefore need to be interpreted with caution.

#### **8.10.2.8 Survival Analyses**

#### **8.10.2.8.1      *Cox proportional-hazards regression analysis***

Separate CPH<sup>13</sup> modeling was to be carried out for each outcome, although as adjudication found no true cases of SLD this analysis was only conducted for the ILD outcome. The CPH model used exposure group (dronedarone as the reference drug) as the main independent variable, and incorporated as explicit covariates the confounders that remained severely unbalanced after propensity score matching. Results have been presented as either crude or adjusted hazard ratios (depending on whether or not unbalanced covariates were included in the model), with 95% confidence intervals and p-values, for each comparator drug relative to dronedarone.

For all models, the Schoenfeld residual test was performed to test the proportionality assumption.<sup>14</sup>

#### **8.10.2.8.2      *Kaplan Meier Survival Estimates***

Graphs displaying separate Kaplan-Meier survival curves for each exposure group were prepared for the ILD outcome.<sup>15</sup> The log-rank test was performed to identify any statistically significant difference between the dronedarone versus comparator drug cohort curves. Like the CPH analysis, Kaplan-Meier curves were not generated for the SLD outcome as no cases were adjudicated as true SLD.

### **8.10.3      Missing values**

Missing values relating to the study outcomes were not encountered. Patient records with missing data, e.g., demographics and comorbid conditions were not observed.

### **8.10.4      Sensitivity analyses**

#### **8.10.4.1      *Addition of Laboratory Data to SLD***

A sensitivity analysis of SLD outcomes was conducted by re-adjudicating cases with the addition of laboratory test results (e.g., alanine transaminase levels, aspartate transaminase levels, bilirubin levels), where available. The goal of this sensitivity analysis was to determine: 1) if those cases are representative of the database population, and 2) if the laboratory information adds value to the existing data.

#### **8.10.4.2      *ILD Sensitivity Analyses***

Three sensitivity analyses were conducted for the ILD outcome by varying the outcome definition (Narrow versus Broad) and risk period (Follow-up period (Risk Period 1) versus Index Treatment Episode (Risk Period 2)).

### 8.10.5 Amendments to the statistical analysis plan

The statistical analysis plan was carried out as planned.

## 8.11 QUALITY CONTROL

Degge implements quality control procedures to verify data analyses. Those include review of programming and results by a second programmer and review of all report tables for reasonable values and consistent totals. Also, the study was conducted in accordance with Guidelines for Good Pharmacoepidemiology Practice established by the International Society of Pharmacoepidemiology and Therapeutic Risk Management.<sup>16</sup>

## 9. RESULTS

A total of 146,333 patients with a new prescription for one of the study drugs of interest dispensed between 20 July 2009 and 31 March 2014 were identified in the DoD database. Patients were assigned to study drug cohorts on the basis of their earliest pharmacy record, dated on or after 20 July 2009, showing one of the study drugs dispensed. **Table 1** shows patient attrition associated with application of each of the initial screening criteria, as described in **Sections 8.3.2** and **8.3.3**. Following the initial screening 51,391 patients remained in the *Final study drug cohorts*. Figure 2 graphically describes the initial screening process.

Patient characteristics and results of outcome analyses are described in the sections that follow, separately for the SLD and ILD analyses. Results of the three ILD sensitivity analyses are provided separately in **Appendix 13**.



**Table 1. Number of Patients with a Study Drug of Interest between 20 July 2009 and 31 March 2014 by Study Drug Cohort and Screening Criteria: DoD Database - 20 July 2009 through 30 September 2014**

| Baseline Exclusionary Screening Description                       | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|-------------------------------------------------------------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Assign the first study drug as the cohort*                        | 15,887       | 100         | 72,639        | 100         | 26,823       | 100         | 16,108       | 100.0       | 3,094      | 100         | 11,782       | 100         |
| Less patients without 365 days of eligibility in baseline period  | 233          | 1.5         | 748           | 1.0         | 735          | 2.7         | 652          | 4.0         | 90         | 2.9         | 302          | 2.6         |
| Less patients without AF in baseline period                       | 2,113        | 13.3        | 19,648        | 27.0        | 6,273        | 23.4        | 4,344        | 27.0        | 340        | 11.0        | 2,584        | 21.9        |
| Less patients with the index drug in baseline period              | 0            | 0.0         | 13,848        | 19.1        | 9,284        | 34.6        | 3,982        | 24.7        | 1,300      | 42.0        | 4,016        | 34.1        |
| Less patients with date of death preceding Index Date             | 4            | 0.03        | 10            | 0.01        | 4            | 0.01        | 2            | 0.01        | 0          | 0.0         | 1            | 0.01        |
| Less patients below 18 years old on Index Date†                   | 0            | 0.0         | 4             | 0.01        | 2            | 0.01        | 3            | 0.02        | 0          | 0.0         | 2            | 0.02        |
| Less patients with cancer or organ transplant in baseline period‡ | 4,118        | 25.9        | 13,452        | 18.5        | 3,209        | 12.0        | 1,771        | 11.0        | 415        | 13.4        | 1,348        | 11.4        |
| Less patients with HIV in baseline period‡                        | 0            | 0.0         | 11            | 0.02        | 4            | 0.01        | 3            | 0.02        | 1          | 0.03        | 2            | 0.02        |
| Less pregnant women†                                              | 5            | 0.03        | 33            | 0.05        | 13           | 0.05        | 23           | 0.14        | 2          | 0.06        | 8            | 0.07        |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>9,414</b> | <b>59.3</b> | <b>24,885</b> | <b>34.3</b> | <b>7,299</b> | <b>27.2</b> | <b>5,328</b> | <b>33.1</b> | <b>946</b> | <b>30.6</b> | <b>3,519</b> | <b>29.9</b> |
|                                                                   |              |             |               |             |              |             |              |             |            |             |              |             |
| Serious Liver Injury/Disease (SLD)                                | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Remaining patients prior to screening for Outcome Cohorts         | 9,414        | 59.3        | 24,885        | 34.3        | 7,299        | 27.2        | 5,328        | 33.1        | 945        | 30.5        | <b>3,519</b> | <b>29.9</b> |
| Less patients with SLD exclusionary codes in baseline period‡     | 593          | 3.7         | 1,977         | 2.7         | 559          | 2.1         | 313          | 1.9         | 87         | 2.8         | 190          | 1.6         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                     | <b>8,821</b> | <b>55.5</b> | <b>22,908</b> | <b>31.5</b> | <b>6,740</b> | <b>25.1</b> | <b>5,015</b> | <b>31.1</b> | <b>858</b> | <b>27.7</b> | <b>3,329</b> | <b>28.3</b> |
|                                                                   |              |             |               |             |              |             |              |             |            |             |              |             |
| Interstitial Lung Disease (ILD) Narrow                            | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Remaining patients prior to screening for Outcome Cohorts         | 9,414        | 59.3        | 24,885        | 34.3        | 7,299        | 27.2        | 5,328        | 33.1        | 945        | 30.5        | <b>3,519</b> | <b>29.9</b> |
| Less patients with ILD (Narrow) exclusionary codes in baseline§   | 1,286        | 8.1         | 6,364         | 8.8         | 1,159        | 4.3         | 413          | 2.6         | 150        | 4.8         | 427          | 3.6         |
| <b>Study Cohorts for ILD (Narrow) Outcome Analysis</b>            | <b>8,128</b> | <b>51.2</b> | <b>18,521</b> | <b>25.5</b> | <b>6,140</b> | <b>22.9</b> | <b>4,915</b> | <b>30.5</b> | <b>795</b> | <b>25.7</b> | <b>3,092</b> | <b>26.2</b> |

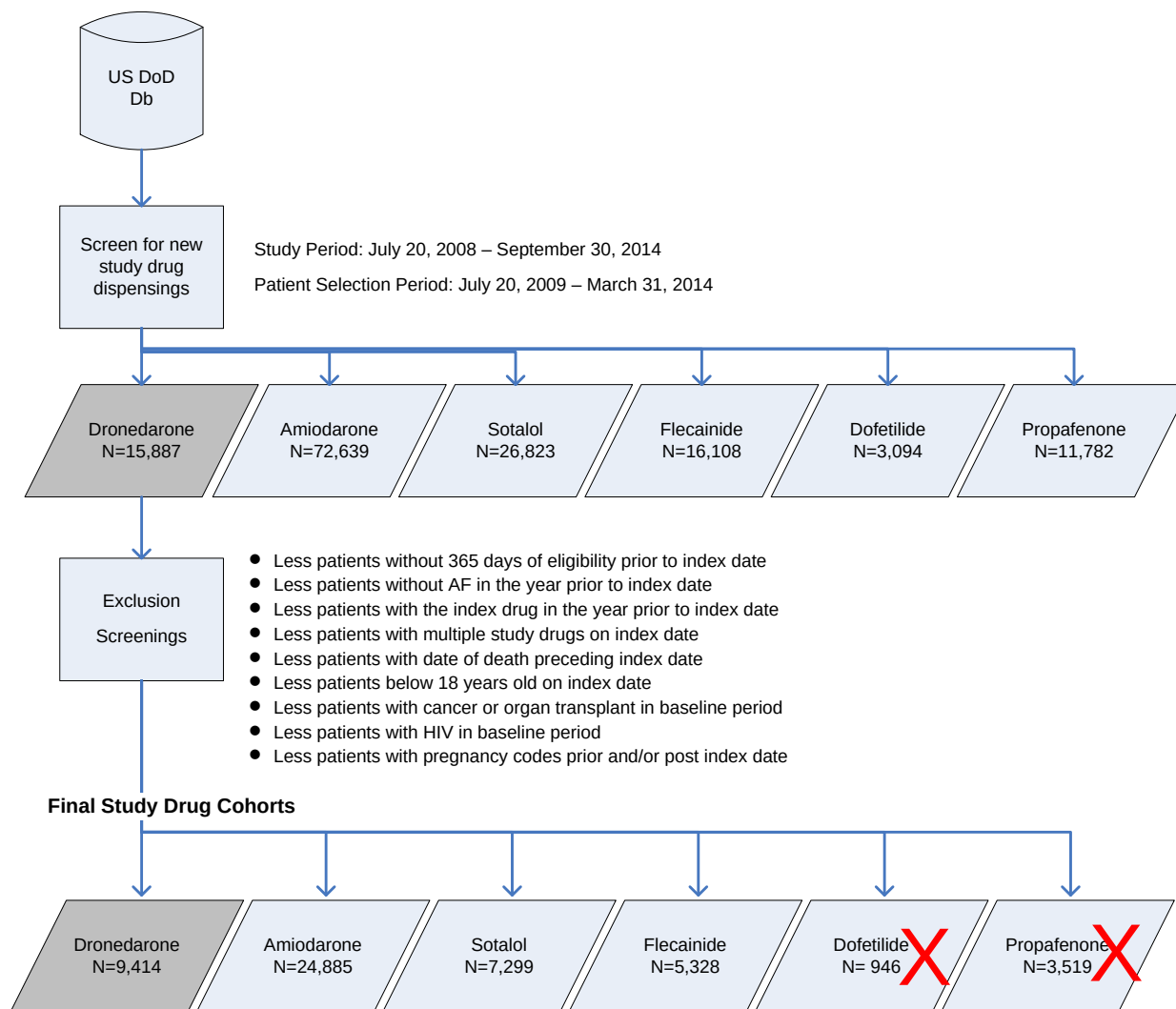
\* Patients with multiple study drugs on the same Index Date were not considered for inclusion in the study.

† Additional screening to reflect Epidemiology Study Protocol.

‡ Includes SLD, viral hepatitis, and hereditary conditions.

§ Includes ILD, pneumonia, and sarcoidosis.

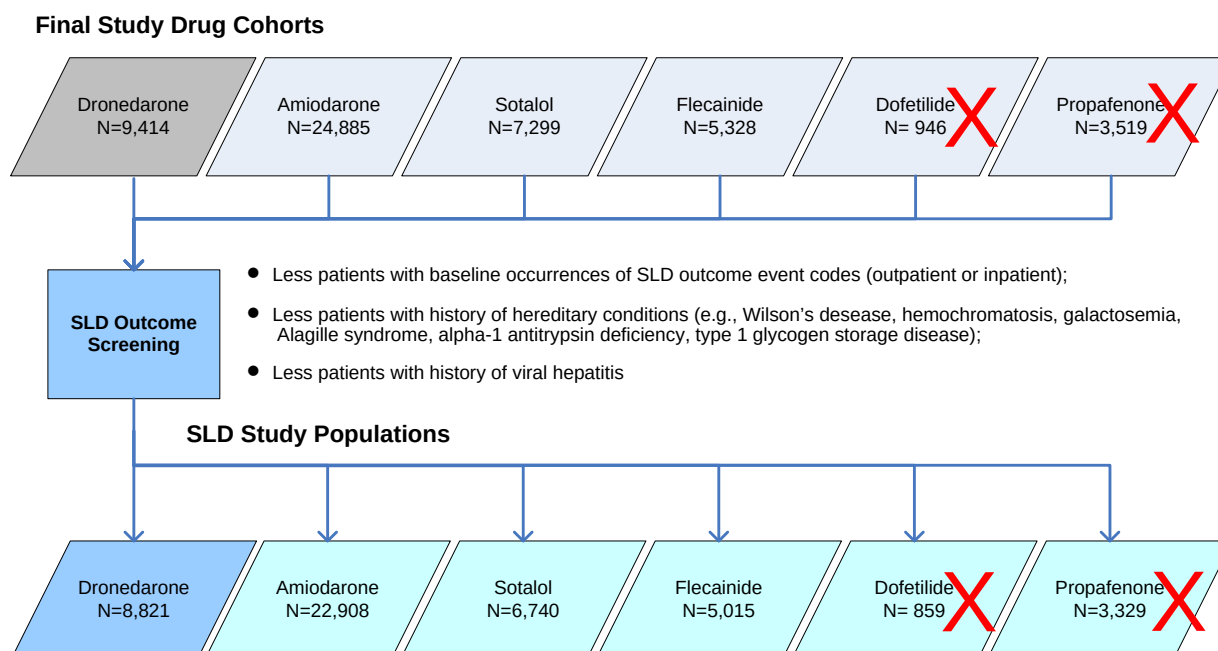
**Figure 2. Identification and Initial Selection Screening to Identify the Study Drug Cohorts; US DOD Database: 20 July 2009 to 30 September 2014**



## 9.1 SLD PATIENT RESULTS

The *SLD study population* was created from the *Final study drug cohorts* by removing those with baseline occurrences of SLD. Following the additional screening, 47,672 patients were retained for the *SLD study population* (see Figure 3).

**Figure 3. SLD Outcome Screening to create the SLD Study Populations; US DOD Database: 20 July 2009 to 30 September 2014**



## 9.1.1 SLD Descriptive data

### 9.1.1.1 Characteristics of Patients in the SLD Study Population Prior to Propensity Score Matching

#### 9.1.1.1.1 Baseline characteristics

**Table 2** presents baseline demographic characteristics, disease and medication use histories for all patients meeting the *SLD study population* inclusion criteria.

Amiodarone users comprised the largest study drug cohort in the *SLD study population*, with more than double the number of patients found in the second largest cohort (n=22,908 versus n=8,821 in the dronedarone cohort).

The propafenone and dofetilide cohorts were the smallest in the *SLD study population*. Both failed to meet the required minimum 3,860 patients (n=3,329 and n=858, respectively), and thus were excluded from the SLD outcome analysis.

#### 9.1.1.1.2 Demographic characteristics

Age varied across study drug cohorts, with the flecainide and propafenone cohorts having relatively younger patients (mean age 64.2 and 67.7 years, respectively) and the amiodarone cohort having the oldest patients, on average (mean age 73.8 years).

Patient distribution by gender also varied across cohorts. Females constituted only about one-third of patients in the dofetilide cohort (34.5%) compared to roughly half the propafenone, flecainide, sotalol, and dronedarone users (51.9%, 50.2%, 47.0%, and 46.9%, respectively).

Race was unknown for more than half the patients in each cohort. In all cohorts, between 84% and 89% of patients with known race were White. No other single racial group accounted for more than 8% of patients with known race in any cohort.

#### 9.1.1.1.3 History of Disease

Patients in the *SLD study population* had relatively low Scores on the Deyo-Charlson Index (DCI), although there was notable variation by cohort. The lowest mean DCI of 0.84 was found in the youngest cohort (flecainide), and the highest (2.2) in the oldest cohort (amiodarone).

**Table 2)**

Differences were also noted in baseline prevalence of the specific diseases reported in **Table 2**.

Congestive heart failure (CHF) appeared in the baseline diagnoses of roughly half the amiodarone and dofetilide patients in the *SLD study population* (52.1% and 44.6%, respectively). In contrast, only 11.6% of patients in the flecainide cohort had baseline CHF diagnoses.

Baseline prevalence of diabetes was also highest in the amiodarone cohort (41.4%). Roughly one third of dofetilide, sotalol and dronedarone patients had a history of diabetes (34.8%, 34.0%, and 32.6%, respectively) and one fifth (19.9%) of the flecainide cohort had baseline records indicating this condition.

Diagnoses identifying baseline obesity were found for between 15% and 16% of patients in five of the study drug cohorts. The exception was the dofetilide group, in which nearly one fourth the patients (23.9%) had baseline obesity. Since BMI measurements are not consistently available in this database, it is possible that obesity diagnoses may be more prevalent in the *SLD study population* than is apparent from observing diagnoses alone.

At most 5% of patients in any cohort had diagnoses suggestive of bile duct disorders in the twelve months preceding their Index Date. Alcoholism diagnoses were also rare. Only 38 patients in the entire study population had baseline diagnoses representing a history of alcoholism, accounting for 0.12% or less of patients in any single cohort; however. As with obesity, alcoholism may be underreported in the MHS.

**Table 2. Baseline Characteristics of Patients in the SLD Study Population according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

| <b>SLD Study Population</b>                | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            | <b>Dofetilide</b> |            | <b>Propafenone</b> |            |
|--------------------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|--------------------|------------|
| <b>Characteristics, N %</b>                | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>           | <b>%</b>   |
| <b>All Patients</b>                        | <b>8,821</b>       | <b>100</b> | <b>22,908</b>     | <b>100</b> | <b>6,740</b>   | <b>100</b> | <b>5,015</b>      | <b>100</b> | <b>858</b>        | <b>100</b> | <b>3,329</b>       | <b>100</b> |
| <b>Demographics</b>                        |                    |            |                   |            |                |            |                   |            |                   |            |                    |            |
| <b>Age at cohort entry date, Mean (SD)</b> | 70.4               | 10.2       | 73.8              | 9.0        | 71.2           | 10.0       | 64.2              | 13.7       | 69.1              | 9.6        | 67.7               | 11.9       |
| 18-39 years                                | 85                 | 1.0        | 62                | 0.3        | 59             | 0.9        | 334               | 6.7        | 6                 | 0.7        | 91                 | 2.7        |
| 40-49 years                                | 244                | 2.8        | 241               | 1.1        | 154            | 2.3        | 400               | 8.0        | 20                | 2.3        | 182                | 5.5        |
| 50-59 years                                | 829                | 9.4        | 1,187             | 5.2        | 499            | 7.4        | 716               | 14.3       | 101               | 11.8       | 378                | 11.4       |
| 60-69 years                                | 2,557              | 29.0       | 5,203             | 22.7       | 1,930          | 28.6       | 1,626             | 32.4       | 280               | 32.6       | 1,053              | 31.6       |
| 70-79 years                                | 3,411              | 38.7       | 9,209             | 40.2       | 2,661          | 39.5       | 1,396             | 27.8       | 338               | 39.4       | 1,130              | 33.9       |
| 80+ years                                  | 1,695              | 19.2       | 7,006             | 30.6       | 1,437          | 21.3       | 543               | 10.8       | 113               | 13.2       | 495                | 14.9       |
| <b>Gender (female)</b>                     | 4,133              | 46.9       | 9,511             | 41.5       | 3,167          | 47.0       | 2,518             | 50.2       | 296               | 34.5       | 1,728              | 51.9       |
| <b>Race</b>                                |                    |            |                   |            |                |            |                   |            |                   |            |                    |            |
| White                                      | 2,853              | 32.3       | 6,253             | 27.3       | 2,003          | 29.7       | 1,986             | 39.6       | 349               | 40.7       | 1,107              | 33.3       |
| Asian or Pacific Islander                  | 75                 | 0.9        | 241               | 1.1        | 57             | 0.8        | 68                | 1.4        | 7                 | 0.8        | 31                 | 0.9        |
| Black                                      | 206                | 2.3        | 528               | 2.3        | 141            | 2.1        | 186               | 3.7        | 23                | 2.7        | 89                 | 2.7        |
| American Indian/Alaskan Native             | 12                 | 0.14       | 40                | 0.2        | 11             | 0.2        | 8                 | 0.2        | 1                 | 0.12       | 6                  | 0.2        |
| Two races reported                         | 36                 | 0.4        | 53                | 0.2        | 22             | 0.3        | 39                | 0.8        | 2                 | 0.2        | 13                 | 0.4        |
| Other                                      | 106                | 1.2        | 211               | 0.9        | 56             | 0.8        | 69                | 1.4        | 11                | 1.3        | 27                 | 0.8        |
| Unknown                                    | 5,533              | 62.7       | 15,582            | 68.0       | 4,450          | 66.0       | 2,659             | 53.0       | 465               | 54.2       | 2,056              | 61.8       |
| <b>History of Disease</b>                  |                    |            |                   |            |                |            |                   |            |                   |            |                    |            |
| Deyo-Charlson Index, Mean (SD)             | 1.5                | 1.7        | 2.2               | 1.9        | 1.5            | 1.6        | 0.8               | 1.2        | 1.5               | 1.6        | 1.1                | 1.4        |
| Alcoholism                                 | 8                  | 0.09       | 15                | 0.07       | 5              | 0.07       | 6                 | 0.12       | 1                 | 0.12       | 3                  | 0.09       |
| Bile Duct Disorders                        | 228                | 2.6        | 1,122             | 4.9        | 203            | 3.0        | 104               | 2.1        | 16                | 1.9        | 76                 | 2.3        |
| Congestive Heart Failure                   | 2,241              | 25.4       | 11,945            | 52.1       | 2,037          | 30.2       | 581               | 11.6       | 383               | 44.6       | 583                | 17.5       |
| Diabetes                                   | 2,872              | 32.6       | 9,488             | 41.4       | 2,290          | 34.0       | 999               | 19.9       | 299               | 34.8       | 824                | 24.8       |
| Obesity                                    | 1,368              | 15.5       | 3,962             | 17.3       | 1,098          | 16.3       | 807               | 16.1       | 205               | 23.9       | 493                | 14.8       |
| <b>History of Medication Use</b>           |                    |            |                   |            |                |            |                   |            |                   |            |                    |            |
| Other Anti-arrhythmic Agents               | 47                 | 0.5        | 112               | 0.5        | 24             | 0.4        | 19                | 0.4        | 5                 | 0.6        | 21                 | 0.6        |
| Use of hepatotoxic medications             | 5,537              | 62.8       | 15,963            | 69.7       | 4,277          | 63.5       | 2,831             | 56.5       | 524               | 61.1       | 2,026              | 60.9       |

#### **9.1.1.1.4 History of Medication Use**

Roughly one half to two thirds of the *SLD study population* had claims during the baseline period for potentially hepatotoxic medications. Acetaminophen (or combination drugs including acetaminophen) was the single most common of the potentially hepatotoxic drugs, found in baseline records of 38.9% of the *SLD study population*. In addition to the commonly used acetaminophen combinations, the list of top five most common potentially hepatotoxic drugs in the *SLD Study population*, and proportions of patients dispensed the drugs at least once in the baseline period, were ciprofloxacin HCL (12.2%), amoxicillin-potassium/clavulanate (8.0%), allopurinol (5.2%), and fenofibrate (5.1%). Patients with these exposures were not excluded from the study population, and their use in the temporal profiles was reviewed by the adjudicators in making their assessments.

Few patients had dispensing records for other anti-arrhythmic agents (0.6% or less of cohort members).

#### **9.1.1.1.5 Post-Index Date Characteristics - SLD Study Population Patient Follow-Up Time**

Follow-up time for patients in the *SLD study population* is summarized in [Table 3](#). The average length of follow-up ranged from 865 days (roughly 29 months) to 1,080 days (roughly 36 months) for all cohorts, with the amiodarone cohort having the shortest follow-up time, and dronedarone the longest.

Corresponding to its shorter average follow-up, the amiodarone cohort had the highest proportion of patients whose follow-up lasted one year or less (22.0% versus 10.6% to 14.5% in other cohorts). In contrast, nearly three-fourths of the dronedarone cohort (72.6%) had more than two years of follow-up, compared to between 54.6% and 68.8% with a follow-up longer than two years among the other study drug cohorts.

#### **9.1.1.1.6 Post-Index Date Characteristics - Index Treatment Episode**

Most patients in the *SLD study population* had one year or less of exposure in the index treatment episode. ([Table 4](#)) The mean length of patients' index treatment episodes ranged from a low of 201 days (approximately seven months) in the amiodarone cohort, to a high of 459 days (approximately 15 months) in the dofetilide cohort. Dronedarone users' mean index treatment episode duration was 341 days (approximately 11 months).

#### **9.1.1.1.7 Non-Index Study Drugs Dispensed**

[Table 4](#) also shows the distribution of patients, by cohort, according to numbers of non-index study drugs dispensed during the follow-up period. Most patients in the *SLD study population* had no record of having been dispensed a study drug, other than their index drug, during the

interval. The amiodarone cohort had, by far, the highest percentage of patients with no other study drug (90.2%). At most, one-third of patients in the dronedarone and propafenone cohorts were dispensed at least one study drug other than the one received on their Index Date. Most of those patients (27.2% and 24.8% of all dronedarone and propafenone patients, respectively) were dispensed only one non-index study drug.

**Table 3. SLD Study Population Follow-up Time according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            | <b>Dofetilide</b> |            | <b>Propafenone</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|--------------------|------------|
| <b>Follow-up Time<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>           | <b>%</b>   |
| <b>All Patients</b>               | <b>8,821</b>       | <b>100</b> | <b>22,908</b>     | <b>100</b> | <b>6,740</b>   | <b>100</b> | <b>5,015</b>      | <b>100</b> | <b>858</b>        | <b>100</b> | <b>3,329</b>       | <b>100</b> |
| 1-90 days                         | 122                | 1.4        | 998               | 4.4        | 121            | 1.8        | 41                | 0.8        | 5                 | 0.6        | 44                 | 1.3        |
| 91-180 days                       | 96                 | 1.1        | 761               | 3.3        | 86             | 1.3        | 38                | 0.8        | 11                | 1.3        | 33                 | 1.0        |
| 181-365 days                      | 720                | 8.2        | 3,279             | 14.3       | 769            | 11.4       | 646               | 12.9       | 99                | 11.5       | 322                | 9.7        |
| 366-545 days                      | 762                | 8.6        | 2,764             | 12.1       | 732            | 10.9       | 569               | 11.4       | 95                | 11.1       | 322                | 9.7        |
| 546-730 days                      | 719                | 8.2        | 2,591             | 11.3       | 766            | 11.4       | 570               | 11.4       | 108               | 12.6       | 319                | 9.6        |
| >730 days                         | 6,402              | 72.6       | 12,515            | 54.6       | 4,266          | 63.3       | 3,151             | 62.8       | 540               | 62.9       | 2,289              | 68.8       |
| Mean                              | 1,080              |            | 865               |            | 988            |            | 975               |            | 985               |            | 1,048              |            |
| Median                            | 1,166              |            | 815               |            | 966            |            | 946               |            | 947               |            | 1,043              |            |
| SD                                | 490.4              |            | 525.8             |            | 519.7          |            | 508.5             |            | 511.7             |            | 516.7              |            |
| Min                               | 4                  |            | 1                 |            | 1              |            | 12                |            | 48                |            | 3                  |            |
| Max                               | 1,894              |            | 1,898             |            | 1,898          |            | 1,898             |            | 1,898             |            | 1,898              |            |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.



**Table 4. SLD Study Population Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                                           | Dronedarone |      | Amiodarone |      | Sotalol |      | Flecainide |      | Dofetilide |      | Propafenone |      |
|-----------------------------------------------------------|-------------|------|------------|------|---------|------|------------|------|------------|------|-------------|------|
| Episode Length <sup>a</sup>                               | N           | %    | N          | %    | N       | %    | N          | %    | N          | %    | N           | %    |
| All Patients                                              | 8,821       | 100  | 22,908     | 100  | 6,740   | 100  | 5,015      | 100  | 858        | 100  | 3,329       | 100  |
| 1-90 days                                                 | 2,688       | 30.5 | 9,665      | 42.2 | 1,711   | 25.4 | 1,802      | 35.9 | 141        | 16.4 | 1,398       | 42.0 |
| 91-180 days                                               | 1,629       | 18.5 | 5,702      | 24.9 | 1,121   | 16.6 | 792        | 15.8 | 124        | 14.5 | 531         | 16.0 |
| 181-365 days                                              | 1,612       | 18.3 | 4,098      | 17.9 | 1,336   | 19.8 | 923        | 18.4 | 178        | 20.7 | 513         | 15.4 |
| 366-545 days                                              | 988         | 11.2 | 1,678      | 7.3  | 894     | 13.3 | 526        | 10.5 | 136        | 15.9 | 281         | 8.4  |
| 546-730 days                                              | 637         | 7.2  | 763        | 3.3  | 550     | 8.2  | 294        | 5.9  | 93         | 10.8 | 185         | 5.6  |
| >730 days                                                 | 1,267       | 14.4 | 1,002      | 4.4  | 1,128   | 16.7 | 678        | 13.5 | 186        | 21.7 | 421         | 12.6 |
| Mean                                                      | 341         |      | 201        |      | 385     |      | 319        |      | 459        |      | 300         |      |
| Median                                                    | 188         |      | 119        |      | 238     |      | 164        |      | 350        |      | 119         |      |
| SD                                                        | 370.1       |      | 233.8      |      | 388.7   |      | 366.3      |      | 399.2      |      | 379.5       |      |
| Min                                                       | 1           |      | 1          |      | 1       |      | 1          |      | 1          |      | 1           |      |
| Max                                                       | 1,886       |      | 1,896      |      | 1,893   |      | 1,898      |      | 1,893      |      | 1,889       |      |
| Number of Non-Index Study Drugs Dispensed Post Index Date |             |      |            |      |         |      |            |      |            |      |             |      |
| 0                                                         | 5,902       | 66.9 | 20,659     | 90.2 | 5,145   | 76.3 | 3,848      | 76.7 | 690        | 80.4 | 2,238       | 67.2 |
| 1                                                         | 2,399       | 27.2 | 1,924      | 8.4  | 1,281   | 19.0 | 879        | 17.5 | 137        | 16.0 | 826         | 24.8 |
| 2                                                         | 445         | 5.0  | 285        | 1.2  | 266     | 3.9  | 233        | 4.6  | 26         | 3.0  | 229         | 6.9  |
| 3                                                         | 65          | 0.7  | 35         | 0.2  | 44      | 0.7  | 51         | 1.0  | 5          | 0.6  | 33          | 1.0  |
| 4                                                         | 10          | 0.11 | 5          | 0.02 | 4       | 0.06 | 4          | 0.08 | 0          | 0.0  | 3           | 0.09 |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.

#### **9.1.1.2 Characteristics of Patients in the SLD PS-matched Analysis Dataset**

The SLD outcome analysis was conducted in the subset of PS-matched patients from the four cohorts in the *SLD Study Population* meeting the minimum size requirement for the study power calculations. That subset is referred to as the *SLD analysis dataset* and consisted of equal numbers of patients from the dronedarone, amiodarone, sotalol and flecainide cohorts (n=4,123 each; total n=16,492). **Table 5** summarizes patient characteristics both before and after PS matching, including standardized differences calculated to compare the dronedarone cohort separately to each of the three comparator cohorts. Standardized differences exceeding a value of 25 (representing a difference of more than 25% of the pooled standard deviation of the compared values) were considered significant in these analyses. **Table 6** summarizes baseline demographic characteristics and selected baseline history of disease and medication use for the PS-matched cohorts.

**Table 5. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Population vs. SLD Analysis Dataset Before and After Propensity Score Matching: DoD Database - 20 July 2009 to 30 September 2014**

|                                              | Prior to PS Matching |       |       |       |                       |      |      | PS-Matched Subsets |       |       |       |                       |      |     |
|----------------------------------------------|----------------------|-------|-------|-------|-----------------------|------|------|--------------------|-------|-------|-------|-----------------------|------|-----|
|                                              | Mean Value or %      |       |       |       | 100*Difference/<br>SD |      |      | Mean Value or %    |       |       |       | 100*Difference/<br>SD |      |     |
| Covariates                                   | MQ                   | AM    | SO    | FL    | AM                    | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                    | SO   | FL  |
| Gender (% female)                            | 46.9%                | 41.5% | 47.0% | 50.2% | 10.8                  | 0.3  | 6.7  | 50.5%              | 49.6% | 47.9% | 50.5% | 1.8                   | 5.3  | 0.0 |
| Age on Index Date (mean)                     | 70.4                 | 73.8  | 71.2  | 64.2  | 36.4                  | 7.7  | 53.6 | 67.8               | 70.5  | 70.5  | 67.3  | 25.9                  | 26.0 | 4.7 |
| Study year of Index Date (mean)              | 2.5                  | 2.9   | 2.8   | 3.0   | 27.9                  | 21.2 | 33.7 | 2.9                | 2.5   | 2.6   | 2.8   | 31.2                  | 22.3 | 5.9 |
| Alcoholism-Y/N                               | 0.09%                | 0.06% | 0.07% | 0.12% | 0.9                   | 0.6  | 0.9  | 0.07%              | 0.05% | 0.07% | 0.12% | 1.0                   | 0.0  | 1.6 |
| Bile Duct Disorders-Y/N                      | 2.6%                 | 4.9%  | 3.0%  | 2.1%  | 11.5                  | 2.6  | 3.3  | 2.3%               | 2.2%  | 2.8%  | 2.2%  | 0.7                   | 3.1  | 0.3 |
| Congestive Heart Failure-Y/N                 | 25.4%                | 52.1% | 30.2% | 11.6% | 55.4                  | 10.8 | 34.8 | 14.1%              | 19.8% | 25.6% | 13.9% | 15                    | 28.9 | 0.6 |
| Diabetes-Y/N                                 | 32.6%                | 41.4% | 34.0% | 19.9% | 18.2                  | 3.0  | 28.4 | 23.6%              | 30.7% | 32.4% | 22.9% | 16                    | 19.7 | 1.5 |
| Obesity-Y/N                                  | 15.5%                | 17.3% | 16.3% | 16.1% | 4.8                   | 2.1  | 1.6  | 15.5%              | 15.4% | 15.3% | 15.8% | 0.2                   | 0.5  | 0.8 |
| Use of other study medications-Y/N           | 3.1%                 | 0.5%  | 1.0%  | 0.8%  | 23.9                  | 14.5 | 15.3 | 1.0%               | 2.3%  | 1.5%  | 0.9%  | 10.2                  | 5.0  | 0.2 |
| Prescription for other anti-arrhythmics-Y/N  | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.6                   | 2.6  | 2.2  | 0.4%               | 0.4%  | 0.4%  | 0.4%  | 0.8                   | 0.0  | 0.0 |
| Prescription for hepatotoxic medications-Y/N | 62.8%                | 69.7% | 63.5% | 56.5% | 14.8                  | 1.4  | 13   | 58.9%              | 61.0% | 62.0% | 58.1% | 4.3                   | 6.4  | 1.6 |
| Hospitalized-Y/N                             | 52.7%                | 78.9% | 67.4% | 40.6% | 60.1                  | 30.4 | 24.3 | 45.6%              | 46.8% | 56.0% | 43.1% | 2.3                   | 20.9 | 5.1 |
| Number of office visits (mean)               | 12.9                 | 12.1  | 11.9  | 11.4  | 8.4                   | 10.8 | 16.2 | 11.5               | 12.7  | 12.5  | 11.9  | 12.9                  | 11.2 | 4.3 |
| Visited ER-Y/N                               | 56.7%                | 62.2% | 60.5% | 56.2% | 11.1                  | 7.6  | 1.2  | 54.9%              | 55.4% | 57.7% | 54.6% | 1.0                   | 5.5  | 0.7 |
| Number of different medications (mean)       | 11.8                 | 12.9  | 11.5  | 9.5   | 19.3                  | 3.6  | 38.6 | 10.3               | 11.5  | 11.5  | 10.1  | 21.6                  | 21.2 | 3.1 |
| Gastroenterology specialty visits-Y/N        | 15.6%                | 15.7% | 14.5% | 12.8% | 0.3                   | 2.9  | 8.0  | 13.4%              | 14.6% | 15.1% | 13.9% | 3.7                   | 5.1  | 1.6 |

Abbreviations: MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 6. Baseline Characteristics of Patients in Each of the SLD Study Drug Cohorts After Propensity Score Matching: DoD Database - 20 July 2009 to 30 September 2014**

| <b>SLD Analysis Dataset</b>         | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            |
|-------------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|
| <b>Characteristics, N %</b>         | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   |
| <b>All Patients</b>                 | <b>4,123</b>       | <b>100</b> | <b>4,123</b>      | <b>100</b> | <b>4,123</b>   | <b>100</b> | <b>4,123</b>      | <b>100</b> |
| <b>Demographics</b>                 |                    |            |                   |            |                |            |                   |            |
| Age at cohort entry date, Mean (SD) | 67.8               | 10.5       | 70.5              | 10.4       | 70.5           | 10.2       | 67.3              | 11.3       |
| 18-39 years                         | 51                 | 1.2        | 41                | 1.0        | 47             | 1.1        | 96                | 2.3        |
| 40-49 years                         | 168                | 4.1        | 113               | 2.7        | 101            | 2.4        | 217               | 5.3        |
| 50-59 years                         | 561                | 13.6       | 378               | 9.2        | 327            | 7.9        | 504               | 12.2       |
| 60-69 years                         | 1,438              | 34.9       | 1,192             | 28.9       | 1,244          | 30.2       | 1,423             | 34.5       |
| 70-79 years                         | 1,381              | 33.5       | 1,558             | 37.8       | 1,610          | 39         | 1,345             | 32.6       |
| 80+ years                           | 524                | 12.7       | 841               | 20.4       | 794            | 19.3       | 538               | 13.0       |
| Gender (female)                     | 2,082              | 50.5       | 2,044             | 49.6       | 1,973          | 47.9       | 2,081             | 50.5       |
| Race                                |                    |            |                   |            |                |            |                   |            |
| White                               | 1,515              | 36.7       | 1,266             | 30.7       | 1,238          | 30.0       | 1,537             | 37.3       |
| Asian or Pacific Islander           | 43                 | 1.0        | 52                | 1.3        | 28             | 0.7        | 50                | 1.2        |
| Black                               | 107                | 2.6        | 107               | 2.6        | 92             | 2.2        | 116               | 2.8        |
| American Indian/Alaskan Native      | 6                  | 0.15       | 10                | 0.2        | 9              | 0.2        | 7                 | 0.2        |
| Two races reported                  | 18                 | 0.4        | 12                | 0.3        | 16             | 0.4        | 26                | 0.6        |
| Other                               | 47                 | 1.1        | 41                | 1.0        | 31             | 0.8        | 46                | 1.1        |
| Unknown                             | 2,387              | 57.9       | 2,635             | 63.9       | 2,709          | 65.7       | 2,341             | 56.8       |
| <b>History of Disease</b>           |                    |            |                   |            |                |            |                   |            |
| Deyo-Charlson Index, Mean (SD)      | 1.1                | 1.4        | 1.5               | 1.6        | 1.4            | 1.6        | 1.0               | 1.3        |
| Alcoholism                          | 3                  | 0.07       | 2                 | 0.0        | 3              | 0.07       | 5                 | 0.12       |
| Bile Duct Disorders                 | 94                 | 2.3        | 90                | 2.2        | 114            | 2.8        | 92                | 2.2        |
| Congestive Heart Failure            | 583                | 14.1       | 815               | 19.8       | 1,054          | 25.6       | 574               | 13.9       |
| Diabetes                            | 973                | 23.6       | 1,265             | 30.7       | 1,336          | 32.4       | 946               | 22.9       |
| Obesity                             | 640                | 15.5       | 637               | 15.4       | 632            | 15.3       | 652               | 15.8       |
| <b>History of Medication Use</b>    |                    |            |                   |            |                |            |                   |            |
| Other Anti-arrhythmic Agents        | 16                 | 0.4        | 18                | 0.4        | 16             | 0.4        | 16                | 0.4        |
| Potentially hepatotoxic medications | 2,429              | 58.9       | 2,516             | 61.0       | 2,557          | 62.0       | 2,396             | 58.1       |

### 9.1.1.2.1 Baseline characteristics

#### 9.1.1.2.1.1 Demographic Characteristics

Most demographic characteristics were well balanced between the dronedarone cohort and each of the three PS-matched comparator cohorts in the *SLD analysis dataset*. Prior to PS matching, significant differences between the dronedarone cohort and one or more of the comparator cohorts were found for six baseline patient characteristics (age, study year of Index Date, congestive heart failure, diabetes, hospitalization, and mean number of different medications). In

the matched data only age, study year of Index Date and congestive heart failure remained unbalanced. After PS-matching mean age and congestive heart failure were both unbalanced between the dronedarone cohort and sotalol cohorts. Age and study year of Index Date remained unbalanced only between the dronedarone and amiodarone cohorts (**Table 5**). Potential confounders remaining unbalanced after PS-matching were explicitly controlled for in the CPH regression used to compare the risk of SLD over time between dronedarone and the relevant comparator cohorts.

With the exception of the flecainide cohort, mean age in the *SLD analysis dataset* was generally lower than in the study population prior to propensity score matching, ranging from 67.3 in the flecainide cohort to 70.5 in the amiodarone and sotalol cohorts. As seen in **Table 5**, mean age was severely unbalanced between the dronedarone cohort and both the amiodarone and flecainide cohorts prior to PS matching (70.4 years mean age for dronedarone versus 73.8 years for amiodarone and 64.2 years for flecainide, standardized difference=36.4 and 53.6, respectively). After matching, mean age was severely unbalanced between the dronedarone cohort and the amiodarone and sotalol cohorts (67.8 years mean age for dronedarone versus 70.5 years for both the amiodarone and sotalol cohorts, standardized difference=25.9 and 26.0, respectively). Mean age of the flecainide cohort was roughly the same as that of the dronedarone cohort in the matched dataset (67.3 years).

The PS-matched data were well balanced by gender, with females comprising roughly half of each cohort (range 47.9% to 50.5%).

Race was unknown for more than half the patients in each PS-matched cohort (range 56.8% to 65.7%). Among patients with known race, between 85% and 88% of each cohort were White. Blacks accounted for about 6% to 7% of patients with known race. The combined group of Asians/Pacific Islanders, American Indian/Alaskan natives, biracial patients, and those reporting Other race accounted for the remaining 6% to 8% of patients with non-missing race in each cohort.

#### **9.1.1.2.1.2 History of Disease**

After PS-matching the mean DCI was lower among patients in the dronedarone, amiodarone and sotalol cohorts (1.1, 1.5 and 1.4, respectively). (**Table 6**) Like the overall *SLD study population*, the amiodarone cohort still had the highest value on this measure of morbidity. In the flecainide cohort, which had the lowest DCI prior to PS-matching, the value in the matched cohort was slightly higher (1.0 vs. 0.84).

The change from pre- to post-PS matching in the proportion of patients with baseline CHF was most dramatic in the dronedarone and amiodarone cohorts, where the percentages dropped by

roughly one-half and two-thirds from the corresponding values prior to PS matching (to 14.1% and 19.8%, respectively). Baseline CHF was also notably lower in the PS-matched analysis population for the sotalol cohort (25.6%), although slightly higher in the flecainide cohort (13.9%). While proportions of dronedarone versus amiodarone and flecainide patients with CHF were severely unbalanced in the overall *SLD study population*, only the proportions of dronedarone versus sotalol patients were severely unbalanced after PS matching. (**Table 5**)

Diabetes remained a highly prevalent baseline condition in the PS-matched cohorts, although the proportions were more similar across cohorts than in the overall *SLD study population* and lower in all but the flecainide cohort. Roughly one-fourth of the PS-matched dronedarone and flecainide cohorts (23.6% and 22.9%, respectively), and one-third of the amiodarone and sotalol cohorts (30.7% and 32.4%, respectively) had indications of diabetes in the matched dataset. Absolute percentage changes in proportion of patients with the condition were greatest in the amiodarone and dronedarone cohorts (41.4% versus 30.7%, and 32.6% versus 23.6% pre- to post-matching, respectively). (**Table 5, Table 6**)

The proportions of patients with obesity diagnoses in the PS-matched data were similar across cohorts, albeit slightly lower than in the overall population (15.5%, 15.4%, 15.3% and 15.8% for the PS-matched dronedarone, amiodarone, sotalol and flecainide cohorts, respectively). (**Table 5, Table 6**)

Bile duct disorders, which were rare in the overall *SLD study population* (less than 5% of any cohort), appeared even less frequently in all but the flecainide cohort after PS-matching. The proportions of patients with diagnoses indicative of bile duct disorders during the 365 days prior to and including their Index Date ranged from 2.2% to 2.8% in the *SLD analysis dataset*. (**Table 6**)

Baseline alcoholism diagnoses, extremely rare prior to PS-matching, were found in records of a total 13 patients in the entire *SLD analysis dataset*. With five patients, the flecainide cohort had the highest number of diagnoses indicating a history of alcoholism in the baseline period. The PS-matched dronedarone, amiodarone, and sotalol cohorts had only two or three patients each with alcoholism. (**Table 6**)

#### **9.1.1.2.1.3 History of Medication Use**

After PS matching, the proportions of patient records identifying baseline use of other anti-arrhythmic agents were equally low in all cohorts, as was seen in the pre-matched data. All cohorts in the *SLD analysis dataset* had roughly 0.4% of patients with pharmacy records for other anti-arrhythmics dispensed. (**Table 5, Table 6**)

Similarly, proportions of patients dispensed potentially hepatotoxic drugs in the baseline period were balanced across cohorts within each of the two datasets. Between 58% and 62% of patients

in the four *SLD analysis dataset* cohorts were dispensed at least one of these drugs during the baseline period. (**Table 6**) The five potentially hepatotoxic drugs dispensed to the highest proportions of patients in the *SLD analysis dataset* were acetaminophen / combination products containing acetaminophen (38.0%), ciprofloxacin (12.7%), amoxicillin-potassium clavulanate (8.2%), diclofenac (5.4%) and fenofibrate (5.1%).

#### 9.1.1.2.2 Post-Index Date Characteristics - Index Treatment Episode

The length of index treatment episodes for patients in the *SLD analysis dataset* is summarized in **Table 7**. The average length of index treatment episode for patients in the analysis dataset ranged from 210 to 391 days by cohort (roughly 7-13 months). The maximum difference of roughly one half year was between the amiodarone and sotalol cohorts.

**Table 7. SLD Analysis Dataset Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

| Follow-up Time <sup>a</sup> | Dronedarone  |            | Amiodarone   |            | Sotalol      |            | Flecainide   |            |
|-----------------------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
|                             | N            | %          | N            | %          | N            | %          | N            | %          |
| <b>All Patients</b>         | <b>4,123</b> | <b>100</b> | <b>4,123</b> | <b>100</b> | <b>4,123</b> | <b>100</b> | <b>4,123</b> | <b>100</b> |
| 1-90 days                   | 1,290        | 31.3       | 1,710        | 41.5       | 1,079        | 26.2       | 1,410        | 34.2       |
| 91-180 days                 | 777          | 18.8       | 1,030        | 25.0       | 711          | 17.2       | 628          | 15.2       |
| 181-365 days                | 798          | 19.4       | 725          | 17.6       | 780          | 18.9       | 770          | 18.7       |
| 366-545 days                | 461          | 11.2       | 286          | 6.9        | 492          | 11.9       | 436          | 10.6       |
| 546-730 days                | 274          | 6.6        | 157          | 3.8        | 311          | 7.5        | 249          | 6.0        |
| >730 days                   | 523          | 12.7       | 215          | 5.2        | 750          | 18.2       | 630          | 15.3       |
| Mean                        | 321          |            | 210          |            | 391          |            | 340          |            |
| Median                      | 179          |            | 119          |            | 235          |            | 186          |            |
| SD                          | 352.5        |            | 248.3        |            | 401.0        |            | 382.4        |            |
| Min                         | 1            |            | 1            |            | 1            |            | 1            |            |
| Max                         | 1,886        |            | 1,824        |            | 1,891        |            | 1,898        |            |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.

### 9.1.2 SLD Outcome Events

SLD outcomes were defined by designated diagnosis and/or procedure codes found in records of hospitalizations with admission dates during patients' index treatment episodes. At least one diagnosis designated as potentially indicative of SLD was identified during the index treatment episode for 32 cases in the *SLD analysis dataset*.

The SLD-IAP members independently reviewed the electronic record profile of each suspected case of SLD to determine the validity of the SLD outcome event. Reviewers were blinded to the identification of the study drugs although they were noted in the profiles. All but one of the 32 cases were adjudicated as "No" (i.e., determined not to be valid SLD outcome events), and one

of the cases was adjudicated as “Indeterminate” (i.e., there was not enough information available to make a definitive decision as to whether or not it was a valid SLD outcome event). (**Table 8**)

**Table 8: SLD Analysis Dataset Numbers and Characteristics of Patients with Adjudicated Serious Liver Injury/Disease Events according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                            | <b>Dronedarone<br/>N=4,123</b> |          | <b>Amiodarone<br/>N=4,123</b> |          | <b>Sotalol<br/>N=4,123</b> |          | <b>Flecainide<br/>N=4,123</b> |          |
|--------------------------------------------|--------------------------------|----------|-------------------------------|----------|----------------------------|----------|-------------------------------|----------|
| <b>Characteristics, N %</b>                | <b>N</b>                       | <b>%</b> | <b>N</b>                      | <b>%</b> | <b>N</b>                   | <b>%</b> | <b>N</b>                      | <b>%</b> |
| All Patients with Suspected Outcome Events | 7                              | 100      | 13                            | 100      | 5                          | 100      | 7                             | 100      |
| <b>Adjudication Determination</b>          |                                |          |                               |          |                            |          |                               |          |
| Yes                                        | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| No                                         | 7                              | 100      | 13                            | 100      | 5                          | 100      | 6                             | 85.7     |
| Indeterminate                              | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 1                             | 14.3     |

**Table 9** provides results of the SLD outcome analysis. Total person-years at risk for this analysis were calculated as the sum of days across all patients’ index treatment episodes, within each cohort. A bootstrap method was used to calculate upper confidence intervals for the incidence rates of 0 (zero) cases. Those calculations indicated that, at most, between 1.2 and 2.2 cases of SLD might be expected in a population similar to the one analyzed for this report. No hazard ratio analyses were conducted for the SLD outcome.

**Table 9: SLD Analysis Dataset Incidence Rates (per 1,000 person-years) and Hazard Ratios of Adjudicated Serious Liver Injury/Disease: DoD Database - 20 July 2009 through 30 September 2014**

|                                        | <b>Dronedarone<br/>N=4,123</b> | <b>Amiodarone<br/>N=4,123</b> | <b>Sotalol<br/>N=4,123</b> | <b>Flecainide<br/>N=4,123</b> |
|----------------------------------------|--------------------------------|-------------------------------|----------------------------|-------------------------------|
| Cases during exposure period           | 0                              | 0                             | 0                          | 0                             |
| Person-Years of exposure <sup>a</sup>  | 3,624.5                        | 2,374.3                       | 4,416.2                    | 3,845.6                       |
| Incidence rate (95% CI)                | 0 (0 - 1.5)                    | 0 (0 - 2.4)                   | 0 (0 - 1.3)                | 0 (0 - 1.4)                   |
| p-value IR difference from Dronedarone | --                             | 1                             | 1                          | 1                             |
| Crude HR (95% CI)                      | Reference                      | N/A                           | N/A                        | N/A                           |
| p-value of Hazard Ratio                | --                             | --                            | --                         | --                            |

<sup>a</sup> Person-years of exposure is the sum of total days in index treatment episodes of all patients in a cohort.

### 9.1.2.1 Other analyses

A planned sensitivity analysis was conducted by re-adjudicating cases with the addition of laboratory data. Only two cases with laboratory data available were found among the 32 with

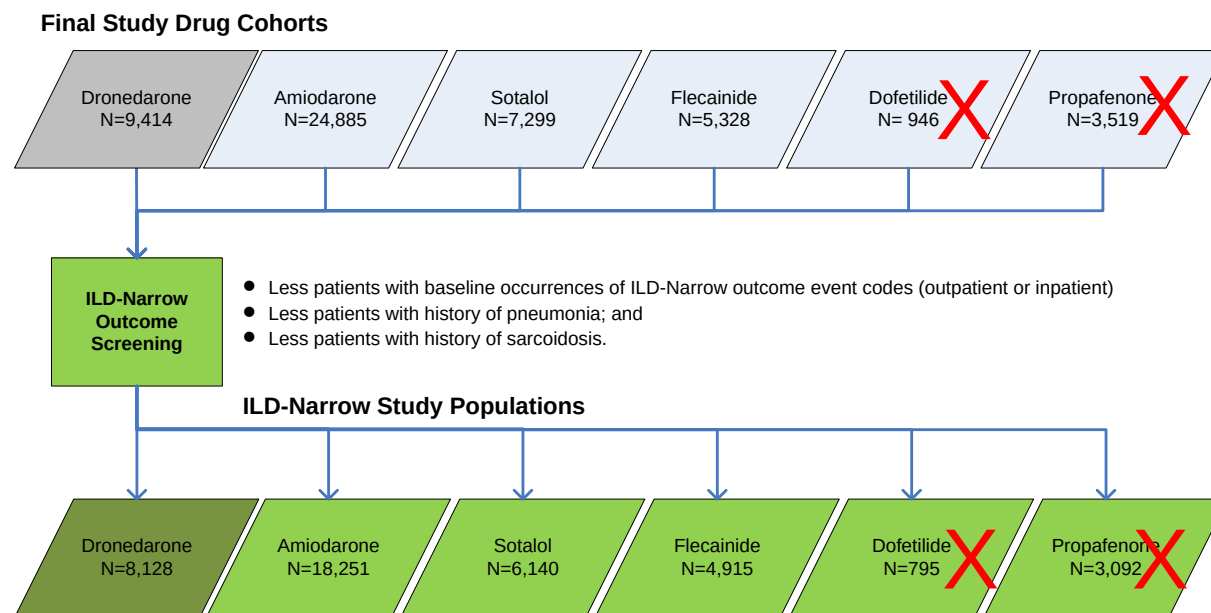
potential SLD, and the adjudication panel maintained its position that the cases did not meet the definition of SLD as defined in the protocol.

## 9.2 ILD NARROW DEFINITION PATIENT RESULTS

### 9.2.1 ILD Narrow Definition Participants

Patients retained after initial screening of the DoD population were further screened to create the *ILD Narrow Definition study population*. Patients with baseline occurrences of ILD, according to the narrow definition used in the study, were removed from the *Final study drug cohorts* to create the *ILD Narrow Definition study population*. A total of 41,591 patients were included in the *ILD Narrow Definition study population* (see Figure 4).

**Figure 4. ILD Outcome Screening to create the ILD Study Populations; US DOD Database: 20 July 2009 to 30 September 2014**



### 9.2.2 ILD Descriptive data

#### 9.2.2.1 Characteristics of Patients in the ILD Narrow Definition Study Population Prior to Propensity Score Matching



#### **9.2.2.1.1 Baseline characteristics**

Baseline demographic characteristics, and medical and medication use histories for all patients meeting the *ILD Narrow Definition study population* inclusion criteria are found in [Table 10](#). Patients with amiodarone as their first study drug exposure on or after the study start comprised the single largest cohort in this population (n=18,521), followed by users of dronedarone (n=8,128), sotalol (n=6,140) and flecainide (4,915). Neither the propafenone nor dofetilide group had adequate numbers of patients to include in the outcome analysis (n=3,092 and n=759, respectively).

##### **9.2.2.1.1.1 Demographic characteristics**

Mean age ranged from 63.7 years to 73.2 years in the *ILD Narrow Definition study population* cohorts. Patients in the flecainide and propafenone cohorts were younger, on average (mean ages 63.7 and 67.1 years, respectively) compared to members of the other study drug cohorts. The oldest patients, on average, were found in the amiodarone cohort.

With regard to gender, females accounted for roughly half the propafenone, flecainide, sotalol, and dronedarone users (51.2%, 49.5%, 46.9%, and 46.5%, respectively). The dofetilide and amiodarone groups were less evenly balanced by gender, with females comprising only 33.6% and 40% of patients in those cohorts, respectively.

Race was unknown for more than half the patients in each *ILD Narrow Definition study population* cohort. The majority of patients with known race were White (between 84% and 88% of each cohort). No other single group accounted for more than 8% of patients with known race in any cohort.

##### **9.2.2.1.1.2 History of Disease**

Mean DCI scores in the *ILD Study population* ranged from 0.8 to 2.0. The flecainide cohort had the smallest average number of comorbidities by this measure, while the relatively older amiodarone cohort had the highest mean DCI. ([Table 10](#))

**Table 10: Baseline Characteristics of Patients in the ILD Narrow Definition Study Population according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

| Characteristics, N %                           | Dronedarone  |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide |            | Propafenone  |            |
|------------------------------------------------|--------------|------------|---------------|------------|--------------|------------|--------------|------------|------------|------------|--------------|------------|
|                                                | N            | %          | N             | %          | N            | %          | N            | %          | N          | %          | N            | %          |
| <b>All Patients</b>                            | <b>8,128</b> | <b>100</b> | <b>18,521</b> | <b>100</b> | <b>6,140</b> | <b>100</b> | <b>4,915</b> | <b>100</b> | <b>795</b> | <b>100</b> | <b>3,092</b> | <b>100</b> |
| <b>Demographics</b>                            |              |            |               |            |              |            |              |            |            |            |              |            |
| Age at cohort entry date, Mean (SD)            | 69.8         | 10.3       | 73.2          | 9.1        | 70.5         | 10.0       | 63.7         | 13.7       | 68.3       | 10.0       | 67.1         | 12.0       |
| 18-39 years                                    | 87           | 1.1        | 58            | 0.3        | 58           | 0.9        | 335          | 6.8        | 10         | 1.3        | 91           | 2.9        |
| 40-49 years                                    | 247          | 3.0        | 219           | 1.2        | 153          | 2.5        | 411          | 8.4        | 21         | 2.6        | 183          | 5.9        |
| 50-59 years                                    | 834          | 10.3       | 1,082         | 5.8        | 506          | 8.2        | 736          | 15.0       | 104        | 13.1       | 371          | 12.0       |
| 60-69 years                                    | 2,456        | 30.2       | 4,503         | 24.3       | 1,854        | 30.2       | 1,616        | 32.9       | 264        | 33.2       | 1,015        | 32.8       |
| 70-79 years                                    | 3,090        | 38.0       | 7,412         | 40.0       | 2,375        | 38.7       | 1,328        | 27.0       | 308        | 38.7       | 1,007        | 32.6       |
| 80+ years                                      | 1,414        | 17.4       | 5,247         | 28.3       | 1,194        | 19.4       | 489          | 9.9        | 88         | 11.1       | 425          | 13.7       |
| Gender (female)                                | 3,779        | 46.5       | 7,487         | 40.4       | 2,878        | 46.9       | 2,431        | 49.5       | 267        | 33.6       | 1,583        | 51.2       |
| Race                                           |              |            |               |            |              |            |              |            |            |            |              |            |
| White                                          | 2,758        | 33.9       | 5,376         | 29.0       | 1,899        | 30.9       | 1,979        | 40.3       | 346        | 43.5       | 1,082        | 35.0       |
| Asian or Pacific Islander                      | 74           | 0.9        | 217           | 1.2        | 56           | 0.9        | 70           | 1.4        | 7          | 0.9        | 29           | 0.9        |
| Black                                          | 193          | 2.4        | 442           | 2.4        | 137          | 2.2        | 185          | 3.8        | 24         | 3.0        | 86           | 2.8        |
| American Indian/Alaskan Native                 | 12           | 0.15       | 33            | 0.2        | 10           | 0.2        | 10           | 0.2        | 2          | 0.3        | 6            | 0.2        |
| Two races reported                             | 32           | 0.4        | 47            | 0.3        | 21           | 0.3        | 39           | 0.8        | 2          | 0.3        | 16           | 0.5        |
| Other                                          | 103          | 1.3        | 185           | 1.0        | 53           | 0.9        | 68           | 1.4        | 11         | 1.4        | 24           | 0.8        |
| Unknown                                        | 4,956        | 61.0       | 12,221        | 66.0       | 3,964        | 64.6       | 2,564        | 52.2       | 403        | 50.7       | 1,849        | 59.8       |
| <b>History of Disease</b>                      |              |            |               |            |              |            |              |            |            |            |              |            |
| Deyo-Charlson Index, Mean (SD)                 | 1.4          | 1.6        | 2.0           | 1.9        | 1.4          | 1.6        | 0.8          | 1.2        | 1.4        | 1.5        | 1.0          | 1.4        |
| Asthma                                         | 831          | 10.2       | 1,802         | 9.7        | 579          | 9.4        | 503          | 10.2       | 94         | 11.8       | 296          | 9.6        |
| Bronchitis                                     | 795          | 9.8        | 2,214         | 12.0       | 612          | 10.0       | 341          | 6.9        | 95         | 11.9       | 243          | 7.9        |
| Chronic Obstructive Pulmonary Disease          | 1,388        | 17.1       | 4,346         | 23.5       | 1,015        | 16.5       | 438          | 8.9        | 156        | 19.6       | 404          | 13.1       |
| Connective Tissue Disease                      | 304          | 3.7        | 708           | 3.8        | 245          | 4.0        | 181          | 3.7        | 25         | 3.1        | 105          | 3.4        |
| Exposure to Toxins                             | 28           | 0.3        | 68            | 0.4        | 12           | 0.2        | 13           | 0.3        | 5          | 0.6        | 15           | 0.5        |
| Gastroesophageal Reflux Disease                | 2,316        | 28.5       | 5,243         | 28.3       | 1,887        | 30.7       | 1,272        | 25.9       | 233        | 29.3       | 848          | 27.4       |
| <b>History of Medication Use</b>               |              |            |               |            |              |            |              |            |            |            |              |            |
| Other Anti-arrhythmic Agents                   | 40           | 0.5        | 93            | 0.5        | 23           | 0.4        | 17           | 0.3        | 5          | 0.6        | 19           | 0.6        |
| Agents assoc. w drug-induced pulmonary disease | 7,541        | 92.8       | 17,631        | 95.2       | 5,561        | 90.6       | 4,292        | 87.3       | 749        | 94.2       | 2,672        | 86.4       |
| Therapeutic Oxygen Treatment                   | 3            | 0.04       | 1             | 0.01       | 1            | 0.02       | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        |

Gastroesophageal reflux disease (GERD) was the most prevalent of the medical conditions considered in the *ILD Study population*. The proportions of patients with diagnoses for this condition were fairly consistent across study drug groups, appearing in 26% - 31% of patient baseline records by cohort. The lowest prevalence was found in the flecainide cohort, and the highest in the dofetilide cohort.

Chronic obstructive pulmonary disease (COPD) was the second most frequently found condition in all but one of the ILD cohorts. Nearly one fourth (23.5%) of the amiodarone cohort, one fifth (19.6%) of the dofetilide cohort, roughly 17% of dronedarone and sotalol patients and 13.1% of propafenone patients were found to have this diagnosis. COPD appeared much less frequently in the flecainide cohort (8.9%), where it was the third most common of the reviewed conditions.

Roughly 10% of patients in all cohorts had asthma diagnoses, and bronchitis appeared in records of 7%-12% of patients. The other medical conditions investigated (connective tissue disease and exposure to toxins) were found in 4% or less of patient records for any cohort.

#### **9.2.2.1.1.3 History of Medication Use**

Agents known to be potentially associated with pulmonary disease appeared in baseline dispensing records of most patients in the study cohorts. The highest proportions of patients with history of these drugs were found in the amiodarone and dofetilide cohorts (95.2% and 94.2%, respectively).

Grouping agents potentially associated with pulmonary disease into broad categories showed the most commonly dispensed were beta-blockers, found in the baseline records of 35.3% of the *ILD Narrow Definition study population*. More than one fourth of the population were dispensed anticoagulants (28.5%), and another fifth had filled ACE inhibitor prescriptions. Completing the list of five most commonly dispensed drugs potentially associated with pulmonary disease were hydrochlorothiazide (or combination products containing hydrochlorothiazide) and nitrofurantoin, appearing respectively in baseline records of 11.4% and 2.2% of the group.

Less than 1% of patients in any cohort had records indicating baseline use of other anti-arrhythmic agents, and a total of five patients had therapeutic oxygen treatments in the baseline period (3 dronedarone, 1 amiodarone and 1 sotalol patients, respectively).

#### **9.2.2.1.2 Post-Index Date Characteristics - Patient Follow-Up Time**

The follow-up period for patients in the *ILD Narrow Definition study population* began on the day after their Index Date and continued through the earliest occurrence of an ILD outcome

event, end of eligibility in the health plan, death, or the end of the study period (i.e., 30 September 2014). Follow-up time for this population is summarized in [Table 11](#).

The average length of follow-up was between 29.9 months and 36.6 months, with the shortest and longest follow-up periods corresponding respectively to the amiodarone and dronedarone cohorts.

#### **9.2.2.1.3 Post-Index Date Characteristics - Index Treatment Episode**

As reported in [Table 12](#), mean length of index treatment episodes in the *ILD Narrow Definition study population* ranged from 202 days (roughly seven months) in the amiodarone cohort, to a high of 450 days (15 months) in the dofetilide cohort. The longest continuous index treatment episodes lasted for approximately five years in all cohorts.

**Table 11: ILD Narrow Definition Study Population Follow-up Time according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |          | <b>Amiodarone</b> |          | <b>Sotalol</b> |          | <b>Flecainide</b> |          | <b>Dofetilide</b> |          | <b>Propafenone</b> |          |
|-----------------------------------|--------------------|----------|-------------------|----------|----------------|----------|-------------------|----------|-------------------|----------|--------------------|----------|
| <b>Follow-up Time<sup>a</sup></b> | <b>N</b>           | <b>%</b> | <b>N</b>          | <b>%</b> | <b>N</b>       | <b>%</b> | <b>N</b>          | <b>%</b> | <b>N</b>          | <b>%</b> | <b>N</b>           | <b>%</b> |
| All Patients                      | 8,128              | 100      | 18,521            | 100      | 6,140          | 100      | 4,915             | 100      | 795               | 100      | 3,092              | 100      |
| 1-90 days                         | 82                 | 1.0      | 592               | 3.2      | 68             | 1.1      | 30                | 0.6      | 2                 | 0.3      | 32                 | 1.0      |
| 91-180 days                       | 65                 | 0.8      | 469               | 2.5      | 56             | 0.9      | 27                | 0.5      | 6                 | 0.8      | 25                 | 0.8      |
| 181-365 days                      | 649                | 8.0      | 2,548             | 13.8     | 691            | 11.3     | 635               | 12.9     | 91                | 11.4     | 294                | 9.5      |
| 366-545 days                      | 679                | 8.4      | 2,244             | 12.1     | 654            | 10.7     | 567               | 11.5     | 83                | 10.4     | 285                | 9.2      |
| 546-730 days                      | 660                | 8.1      | 2,073             | 11.2     | 719            | 11.7     | 557               | 11.3     | 87                | 10.9     | 294                | 9.5      |
| >730 days                         | 5,993              | 73.7     | 10,595            | 57.2     | 3,952          | 64.4     | 3,099             | 63.1     | 526               | 66.2     | 2,162              | 69.9     |
|                                   |                    |          |                   |          |                |          |                   |          |                   |          |                    |          |
| Mean                              | 1,097              |          | 898               |          | 1,006          |          | 979               |          | 1,001             |          | 1,062              |          |
| Median                            | 1,183              |          | 857               |          | 986            |          | 950               |          | 970               |          | 1,063              |          |
| SD                                | 484.3              |          | 521.0             |          | 515.2          |          | 506.6             |          | 498.3             |          | 514.0              |          |
| Min                               | 7                  |          | 1                 |          | 1              |          | 12                |          | 48                |          | 3                  |          |
| Max                               | 1,894              |          | 1,898             |          | 1,898          |          | 1,898             |          | 1,898             |          | 1,898              |          |

<sup>a</sup> Follow-up time is calculated as time from Index Date to the earliest of either and ILD outcome, end of health plan eligibility, date of death or end of study.

**Table 12: ILD Narrow Definition Study Population Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            | <b>Dofetilide</b> |            | <b>Propafenone</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|--------------------|------------|
| <b>Episode Length<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>           | <b>%</b>   |
| <b>All Patients</b>               | <b>8,128</b>       | <b>100</b> | <b>18,521</b>     | <b>100</b> | <b>6,140</b>   | <b>100</b> | <b>4,915</b>      | <b>100</b> | <b>795</b>        | <b>100</b> | <b>3,092</b>       | <b>100</b> |
| 1-90 days                         | 2,423              | 29.8       | 7,822             | 42.2       | 1,511          | 24.6       | 1,760             | 35.8       | 138               | 17.4       | 1,314              | 42.5       |
| 91-180 days                       | 1,507              | 18.5       | 4,623             | 25.0       | 1,003          | 16.3       | 778               | 15.8       | 116               | 14.6       | 488                | 15.8       |
| 181-365 days                      | 1,512              | 18.6       | 3,265             | 17.6       | 1,225          | 20.0       | 897               | 18.3       | 173               | 21.8       | 479                | 15.5       |
| 366-545 days                      | 909                | 11.2       | 1,368             | 7.4        | 838            | 13.6       | 518               | 10.5       | 112               | 14.1       | 252                | 8.2        |
| 546-730 days                      | 586                | 7.2        | 610               | 3.3        | 507            | 8.3        | 292               | 5.9        | 84                | 10.6       | 165                | 5.3        |
| >730 days                         | 1,191              | 14.7       | 833               | 4.5        | 1,056          | 17.2       | 670               | 13.6       | 172               | 21.6       | 394                | 12.7       |
| Mean                              | 345                |            | 202               |            | 392            |            | 321               |            | 450               |            | 299                |            |
| Median                            | 192                |            | 119               |            | 247            |            | 165               |            | 332               |            | 119                |            |
| SD                                | 372.4              |            | 237.6             |            | 392.1          |            | 368.5             |            | 394.8             |            | 384.7              |            |
| Min                               | 1                  |            | 1                 |            | 1              |            | 1                 |            | 1                 |            | 1                  |            |
| Max                               | 1,886              |            | 1,896             |            | 1,893          |            | 1,898             |            | 1,891             |            | 1,889              |            |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.

#### **9.2.2.1.4 Number of Index Drug Treatment Episodes**

As potential ILD outcomes were identified through the end of the follow-up period for the ILD primary analysis, counts of all individual index drug treatment episodes during the follow-up period, by cohort, are reported in [Table 13](#). On average, patients in the *ILD Narrow Definition study population* cohorts had between one and two episodes of treatment with their index drug during the follow-up period, with roughly two-thirds of patients in all cohorts found to have only one treatment episode (minimum 62.4% of the flecainide cohort, to maximum 68.8% of the dronedarone cohort). At most, patients had between 10 and 19 individual index drug treatment episodes by cohort.

#### **9.2.2.1.5 Non-Index Study Drugs Dispensed**

Most patients in the *ILD Narrow Definition study population* had no record of having been dispensed a study drug, other than their index drug, during the interval following their Index Date. ([Table 13](#)) The dronedarone and propafenone cohorts had the highest percentages of patients dispensed at least one prescription for a non-index study drug (33.8% and 33.2%, respectively). Only 11% of the amiodarone cohort had records of at least one other study drug dispensed during the follow-up period.

#### **9.2.2.2 Characteristics of Patients in the ILD Narrow Definition PS-matched Analysis Dataset**

Following the ILD outcome specific screening, three comparator cohorts had the minimum required number of cases for inclusion in the PS-matched *ILD Narrow Definition analysis dataset*. Those were the amiodarone, sotalol and flecainide cohorts. The four cohorts had 4,087 patients each, for a total of 16,348 patients. Standardized differences comparing dronedarone patient characteristics versus each of the comparator cohorts, both before and after PS matching, are found in [Table 14](#). Baseline demographic characteristics and selected baseline disease and medication use history for the PS-matched cohorts are summarized in [Table 15](#).

**Table 13: ILD Narrow Definition Study Population Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed according to Study Drug Cohort: DoD Database - 20 July 2009 to 30 September 2014**

| Drug Treatment Episodes                                   | Dronedarone |      | Amiodarone |      | Sotalol |      | Flecainide |      | Dofetilide |      | Propafenone |      |
|-----------------------------------------------------------|-------------|------|------------|------|---------|------|------------|------|------------|------|-------------|------|
| All Patients                                              | 8,128       | 100  | 18,521     | 100  | 6,140   | 100  | 4,915      | 100  | 795        | 100  | 3,092       | 100  |
| Index Drug Treatment Episodes                             |             |      |            |      |         |      |            |      |            |      |             |      |
| 1                                                         | 5,588       | 68.8 | 12,227     | 66.0 | 3,855   | 62.8 | 3,067      | 62.4 | 535        | 67.3 | 2,070       | 66.9 |
| 2                                                         | 1,449       | 17.8 | 3,375      | 18.2 | 1,201   | 19.6 | 958        | 19.5 | 156        | 19.6 | 527         | 17.0 |
| 3                                                         | 595         | 7.3  | 1,488      | 8.0  | 544     | 8.9  | 440        | 9.0  | 56         | 7.0  | 251         | 8.1  |
| 4+                                                        | 496         | 6.1  | 1,431      | 7.7  | 540     | 8.8  | 450        | 9.2  | 48         | 6.0  | 244         | 7.9  |
|                                                           |             |      |            |      |         |      |            |      |            |      |             |      |
| Average                                                   | 1.6         |      | 1.7        |      | 1.7     |      | 1.8        |      | 1.6        |      | 1.7         |      |
| Median                                                    | 1           |      | 1          |      | 1       |      | 1          |      | 1          |      | 1           |      |
| SD                                                        | 1.2         |      | 1.2        |      | 1.4     |      | 1.4        |      | 1.1        |      | 1.3         |      |
| Min                                                       | 1           |      | 1          |      | 1       |      | 1          |      | 1          |      | 1           |      |
| Max                                                       | 14          |      | 14         |      | 19      |      | 17         |      | 10         |      | 16          |      |
| Number of Non-Index Study Drugs Dispensed Post Index Date |             |      |            |      |         |      |            |      |            |      |             |      |
| 0                                                         | 5,384       | 66.2 | 1,6513     | 89.2 | 4,630   | 75.4 | 3,755      | 76.4 | 632        | 79.5 | 2,067       | 66.8 |
| 1                                                         | 2,242       | 27.6 | 1,703      | 9.2  | 1,201   | 19.6 | 873        | 17.8 | 136        | 17.1 | 770         | 24.9 |
| 2                                                         | 423         | 5.2  | 265        | 1.4  | 262     | 4.3  | 233        | 4.7  | 25         | 3.1  | 222         | 7.2  |
| 3                                                         | 68          | 0.8  | 35         | 0.2  | 43      | 0.7  | 50         | 1.0  | 2          | 0.3  | 30          | 1.0  |
| 4                                                         | 11          | 0.14 | 5          | 0.03 | 4       | 0.07 | 4          | 0.08 | 0          | 0.0  | 3           | 0.10 |



**Table 14: Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Narrow Definition Population vs. ILD Narrow Definition Analysis Dataset: DoD Database - 20 July 2009 to 30 September 2014**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                       | 46.5%                | 40.4% | 46.9% | 49.5% | 12.3              | 0.8  | 5.9  | 48.8%              | 48.5% | 47.5% | 49.4% | 0.6               | 2.6  | 1.2 |
| Age on Index Date (mean)                | 69.8                 | 73.2  | 70.5  | 63.7  | 35.9              | 7.5  | 52.1 | 67.3               | 69.6  | 70.1  | 66.7  | 21.9              | 26.7 | 5.7 |
| Study year of Index Date (mean)         | 2.5                  | 2.9   | 2.8   | 3.0   | 28.1              | 21.2 | 34.0 | 2.9                | 2.6   | 2.7   | 2.9   | 26.9              | 19.5 | 5.6 |
| Toxin exposure-Y/N                      | 0.3%                 | 0.4%  | 0.2%  | 0.3%  | 0.4               | 2.8  | 1.4  | 0.3%               | 0.12% | 0.2%  | 0.3%  | 3.3               | 2.1  | 0.9 |
| Asthma-Y/N                              | 10.2%                | 9.7%  | 9.4%  | 10.2% | 1.7               | 2.7  | 0.0  | 9.4%               | 9.8%  | 9.7%  | 10.3% | 1.3               | 0.8  | 2.9 |
| COPD-Y/N                                | 17.1%                | 23.5% | 16.5% | 8.9%  | 15.6              | 1.5  | 23.7 | 12.9%              | 17.2% | 15.6% | 10.2% | 12.1              | 7.8  | 8.6 |
| Bronchitis-Y/N                          | 9.8%                 | 12.0% | 10.0% | 6.9%  | 6.9               | 0.6  | 10.1 | 7.6%               | 9.5%  | 9.7%  | 7.6%  | 6.7               | 7.5  | 0.0 |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.6               | 1.2  | 2.4  | 0.0%               | 0.02% | 0.02% | 0.0%  | 2.2               | 2.2  | 0.0 |
| Gastroesophageal Reflux-Y/N             | 28.5%                | 28.3% | 30.7% | 25.9% | 0.4               | 4.9  | 5.9  | 27.3%              | 28.1% | 28.6% | 27.6% | 1.9               | 2.9  | 0.7 |
| Connective Tissue Disease-Y/N           | 3.7%                 | 3.8%  | 4.0%  | 3.7%  | 0.4               | 1.3  | 0.3  | 3.6%               | 3.8%  | 3.6%  | 4.2%  | 1.0               | 0.1  | 2.8 |
| Hospitalized-Y/N                        | 49.4%                | 75.2% | 65.0% | 38.7% | 57.0              | 32.0 | 21.6 | 42.8%              | 44.9% | 52.9% | 40.9% | 4.4               | 20.4 | 3.9 |
| Potentially ILD inducing medication-Y/N | 92.8%                | 95.2% | 90.6% | 87.3% | 10.6              | 8.1  | 18.9 | 89.9%              | 92.8% | 92.0% | 90.1% | 10.1              | 7.3  | 0.5 |
| Pulmonology specialty visits-Y/N        | 14.1%                | 20.5% | 12.8% | 11.0% | 16.7              | 3.7  | 9.1  | 11.0%              | 11.9% | 13.4% | 11.6% | 2.6               | 7.2  | 1.7 |
| Other study drug-Y/N                    | 3.0%                 | 0.5%  | 0.9%  | 0.7%  | 22.2              | 14.5 | 16.0 | 0.7%               | 2.1%  | 1.4%  | 0.8%  | 11.4              | 6.2  | 1.1 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.3%  | 0.1               | 1.8  | 2.2  | 0.5%               | 0.5%  | 0.5%  | 0.4%  | 0.7               | 0.4  | 1.9 |
| Number of office visits (mean)          | 12.5                 | 11.8  | 11.8  | 11.2  | 8.5               | 8.5  | 15.0 | 11.2               | 12.2  | 12.0  | 11.7  | 12.1              | 10   | 6.6 |
| Visited ER-Y/N                          | 54.6%                | 58.3% | 58.1% | 55.5% | 7.5               | 7.2  | 1.8  | 53.7%              | 53.8% | 55.8% | 53.5% | 0.3               | 4.3  | 0.3 |
| Number of different medications (mean)  | 11.3                 | 12.3  | 11.1  | 9.3   | 18.0              | 2.5  | 36.1 | 10.0               | 11.2  | 11.1  | 9.8   | 21.1              | 20.9 | 2.3 |

Abbreviations MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 15: Baseline Characteristics of Patients in the ILD Narrow Definition Analysis Dataset according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                         | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            |
|-----------------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|
| <b>Characteristics, N %</b>             | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   |
| <b>All Patients</b>                     | <b>4,087</b>       | <b>100</b> | <b>4,087</b>      | <b>100</b> | <b>4,087</b>   | <b>100</b> | <b>4,087</b>      | <b>100</b> |
| <b>Demographics</b>                     |                    |            |                   |            |                |            |                   |            |
| Age at cohort entry date, Mean (SD)     | 67.3               | 10.4       | 69.6              | 10.4       | 70.1           | 10.2       | 66.7              | 11.4       |
| 18-39 years                             | 54                 | 1.3        | 48                | 1.2        | 47             | 1.1        | 108               | 2.6        |
| 40-49 years                             | 187                | 4.6        | 116               | 2.8        | 104            | 2.5        | 228               | 5.6        |
| 50-59 years                             | 560                | 13.7       | 436               | 10.7       | 355            | 8.7        | 548               | 13.4       |
| 60-69 years                             | 1,478              | 36.2       | 1,297             | 31.7       | 1,293          | 31.6       | 1,436             | 35.1       |
| 70-79 years                             | 1,355              | 33.2       | 1,447             | 35.4       | 1,540          | 37.7       | 1,281             | 31.3       |
| 80+ years                               | 453                | 11.1       | 743               | 18.2       | 748            | 18.3       | 486               | 11.9       |
| Gender (female)                         | 1,994              | 48.8       | 1,982             | 48.5       | 1,940          | 47.5       | 2,018             | 49.4       |
| Race                                    |                    |            |                   |            |                |            |                   |            |
| White                                   | 1,564              | 38.3       | 1,308             | 32.0       | 1,272          | 31.1       | 1,562             | 38.2       |
| Asian or Pacific Islander               | 48                 | 1.2        | 57                | 1.4        | 30             | 0.7        | 51                | 1.2        |
| Black                                   | 115                | 2.8        | 122               | 3.0        | 99             | 2.4        | 129               | 3.2        |
| American Indian/Alaskan Native          | 8                  | 0.2        | 10                | 0.2        | 8              | 0.2        | 7                 | 0.2        |
| Two races reported                      | 17                 | 0.4        | 10                | 0.2        | 15             | 0.4        | 26                | 0.6        |
| Other                                   | 49                 | 1.2        | 46                | 1.1        | 37             | 0.9        | 53                | 1.3        |
| Unknown                                 | 2,286              | 55.9       | 2,534             | 62.0       | 2,626          | 64.3       | 2,259             | 55.3       |
| <b>History of Disease</b>               |                    |            |                   |            |                |            |                   |            |
| Deyo-Charlson Index, Mean (SD)          | 1.1                | 1.5        | 1.6               | 1.7        | 1.4            | 1.6        | 0.9               | 1.3        |
| Asthma                                  | 385                | 9.4        | 401               | 9.8        | 395            | 9.7        | 420               | 10.3       |
| Bronchitis                              | 311                | 7.6        | 387               | 9.5        | 397            | 9.7        | 311               | 7.6        |
| Chronic Obstructive Pulmonary Disease   | 527                | 12.9       | 704               | 17.2       | 638            | 15.6       | 415               | 10.2       |
| Connective Tissue Disease               | 149                | 3.6        | 157               | 3.8        | 148            | 3.6        | 171               | 4.2        |
| Exposure to Toxins                      | 11                 | 0.3        | 5                 | 0.12       | 7              | 0.2        | 13                | 0.3        |
| Gastroesophageal Reflux Disease         | 1,115              | 27.3       | 1,149             | 28.1       | 1,169          | 28.6       | 1,128             | 27.6       |
| <b>History of Medication Use</b>        |                    |            |                   |            |                |            |                   |            |
| Other Anti-arrhythmic Agents            | 20                 | 0.5        | 22                | 0.5        | 19             | 0.5        | 15                | 0.4        |
| Agents assoc w drug-induced pulmon dis. | 3,676              | 89.9       | 3,792             | 92.8       | 3,761          | 92.0       | 3,682             | 90.1       |
| Therapeutic Oxygen Treatment            | 0                  | 0.0        | 1                 | 0.02       | 1              | 0.02       | 0                 | 0.0        |

### 9.2.2.2.1 Baseline characteristics

#### 9.2.2.2.1.1 Demographic Characteristics

Four patient characteristics were severely unbalanced between dronedarone and at least one other cohort prior to PS matching. Those were mean age on Index Date, mean study year of Index Date, hospitalized in baseline, and number of different medications dispensed in baseline. After PS matching, only mean age on Index Date and mean study year of Index Date were still severely unbalanced between the dronedarone cohort and one of the comparator groups. (Table 14)

Mean age in the PS-matched *ILD Narrow Definition analysis dataset* is lower than in the *ILD Narrow Definition study population* among dronedarone, amiodarone and sotalol patients (range 66.7 years to 70.0 years, after PS-matching), and higher in the flecainide cohort (66.7 years after PS-matching). Only the difference between the dronedarone and sotalol cohorts was severely unbalanced after the PS matching (standardized difference=26.7).

The mean study year of patient's Index Date was higher and severely unbalanced in both the amiodarone and flecainide cohorts compared to the dronedarone cohort prior to PS matching. After matching the mean study year of patient's Index Date was still severely unbalanced between the dronedarone and amiodarone cohorts, although the direction of the difference was reversed (standardized difference=26.9). The dronedarone and flecainide cohorts, however, were not severely unbalanced after PS matching.

Prior to PS matching, proportions of patients with at least one baseline hospitalization were notably higher in the amiodarone and sotalol cohorts than in the dronedarone cohort, and the respective standardized differences indicated severe unbalance. Those differences were diminished after PS matching.

Flecainide patients, on average, filled prescriptions for fewer different medications in the baseline than did dronedarone patients in both the *ILD Narrow Definition study population* and the *ILD Narrow Definition analysis dataset*. However, while that difference indicated severe unbalance between the two cohorts for that measure prior to PS matching it was well balanced after PS-matching (standardized difference=36.1 prior to PS matching versus standardized difference=2.3 after PS matching).

Other demographic characteristics were distributed similarly in the pre- and post-PS-matched data.

#### 9.2.2.2.1.2 History of Disease

With regard to number of comorbidities after PS-matching, mean DCI was lower among patients in the dronedarone and amiodarone cohorts (1.1 and 1.6, respectively) and the same or slightly higher in the sotalol and flecainide cohorts (1.4 and 0.9, respectively). ([Table 15](#))

Proportions of patients in the *ILD Narrow Definition analysis dataset* with baseline GERD were somewhat lower than in the overall study population for the dronedarone, amiodarone and sotalol cohorts (27.3%, 28.1% and 28.6%, respectively) and slightly higher in the flecainide cohort (27.6%). Still, the proportions were similar across the four cohorts, both before and after matching.

Percentages of each cohort with COPD were fairly equal in the PS-matched data, and notably lower than in the pre-matched data for all but the flecainide cohort. Among the PS-matched dronedarone, amiodarone and sotalol cohorts, 12.9%, 17.2% and 15.6% of patients, respectively, had baseline COPD diagnoses. As with other morbidities, the proportion of the flecainide cohort with COPD was slightly higher in the PS-matched subset of patients (10.2%), than prior to PS matching.

Asthma appeared in fairly similar proportions of patients, by cohort, both before and after PS matching. Roughly one tenth of each PS-matched cohort had asthma diagnoses in their baseline records.

Proportions of patients with baseline bronchitis diagnoses were also consistent across cohorts in the *ILD Narrow Definition analysis dataset*, ranging from 7.6% of the dronedarone and flecainide cohorts to 9.7% of the sotalol cohort.

Prevalence of connective tissue disease was consistently low across the PS-matched cohorts, ranging from 3.6% of the dronedarone and sotalol cohorts to 4.2% of the flecainide cohort.

Exposure to toxins was rare among PS-matched patients, appearing in diagnoses of 0.3% or less of patients in each cohort.

#### 9.2.2.2.1.3 History of Medication Use

As in the overall *ILD Narrow Definition study population*, use of other anti-arrhythmics in the baseline was rare in the PS-matched cohorts. ([Table 14](#), [Table 15](#)) Only 76 patients in the entire *ILD Narrow Definition analysis dataset* had records indicating that they were dispensed other anti-arrhythmics. Those cases were fairly evenly distributed, representing between 0.4% and 0.5% of any one study drug cohort.

Proportions of patients dispensed agents associated with drug-induced pulmonary disease were also fairly balanced across cohorts of the analysis dataset. Roughly 90% of patients in each cohort had been dispensed at least one of these drugs. Those proportions in the PS-matched data were slightly lower than the corresponding proportions in the overall *ILD Narrow Definition study population* for the dronedarone and amiodarone cohorts, and slightly higher in the sotalol and flecainide cohorts.

About one third of patients in the *ILD Narrow Definition analysis dataset* had filled at least one prescription for a beta-blocker or anticoagulant (34.7% and 30.4%, respectively). Those were the most common potentially ILD inducing drugs found in the baseline records of patients in the ILD primary analysis. Completing the five most common drugs potentially associated with narrow definition ILD were ace inhibitors, hydrochlorothiazide, and nitrofurantoin, which were found respectively in the dispensing histories of 17.8%, 12.1% and 2.2% of patients.

As prior to PS matching, a total of two patients in the *ILD Narrow Definition analysis dataset* had records of receiving therapeutic oxygen treatment. Those appeared, one each, in the amiodarone and sotalol cohorts.

#### **9.2.2.2.2 Post-Index Date Characteristics**

##### **9.2.2.2.2.1 Patient Follow-Up Time**

Follow-up time for patients in the *ILD Narrow Definition analysis dataset* is summarized in **Table 16**. The average length of follow-up was similar for the four cohorts in the PS-matched data, falling between 985 days (32.8 months) and 1,054 days (35.1 months). The shortest and longest mean follow-up intervals were associated, respectively, with the dronedarone and sotalol cohorts.

**Table 16: ILD Narrow Definition Analysis Dataset Follow-up Time according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

| Follow-up Time <sup>a</sup> | Dronedarone  |            | Amiodarone   |            | Sotalol      |            | Flecainide   |            |
|-----------------------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
|                             | N            | %          | N            | %          | N            | %          | N            | %          |
| <b>All Patients</b>         | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> |
| 1-90 days                   | 27           | 0.7        | 68           | 1.7        | 45           | 1.1        | 25           | 0.6        |
| 91-180 days                 | 25           | 0.6        | 85           | 2.1        | 38           | 0.9        | 19           | 0.5        |
| 181-365 days                | 460          | 11.3       | 366          | 9.0        | 388          | 9.5        | 473          | 11.6       |
| 366-545 days                | 476          | 11.6       | 367          | 9.0        | 373          | 9.1        | 405          | 9.9        |
| 546-730 days                | 474          | 11.6       | 347          | 8.5        | 391          | 9.6        | 406          | 9.9        |
| >730 days                   | 2,625        | 64.2       | 2,854        | 69.8       | 2,852        | 70.0       | 2,759        | 67.5       |
| Mean                        | 985          |            | 1,043        |            | 1,054        |            | 1,025        |            |
| Median                      | 985          |            | 1,089        |            | 1,090        |            | 1,025        |            |
| SD                          | 490.9        |            | 507.9        |            | 500.8        |            | 503.1        |            |
| Min                         | 8            |            | 3            |            | 8            |            | 12           |            |
| Max                         | 1,887        |            | 1,898        |            | 1,898        |            | 1,898        |            |

<sup>a</sup> Follow-up time is calculated as time from Index Date through the earliest of either end of eligibility, end of study or date of death.

#### 9.2.2.2.2 Index Treatment Episode

**Table 17** reports on lengths of index treatment episodes for patients' in the *ILD Narrow Definition analysis dataset*, according to study drug cohort. While more similar than prior to PS matching, lengths of index treatment episodes still varied across cohorts. The mean length of patients' index treatment episodes ranged from a low of 221 days (7.4 months) in the amiodarone cohort, to a high of 397 days (13.2 months) in the sotalol cohort. Index treatment episodes lasted less than one year for most patients, with median lengths ranging from 119 days in the amiodarone cohort (4 months) to 244 days in the sotalol cohort (8.1 months).

**Table 17: ILD Narrow Definition Analysis Dataset Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

| Episode Length <sup>a</sup> | Dronedarone  |            | Amiodarone   |            | Sotalol      |            | Flecainide   |            |
|-----------------------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
|                             | N            | %          | N            | %          | N            | %          | N            | %          |
| <b>All Patients</b>         | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> | <b>4,087</b> | <b>100</b> |
| 1-90 days                   | 1,243        | 30.4       | 1,593        | 39.0       | 1,035        | 25.0       | 1,387        | 33.9       |
| 91-180 days                 | 783          | 19.2       | 1,087        | 26.6       | 686          | 17.0       | 622          | 15.2       |
| 181-365 days                | 824          | 20.2       | 716          | 17.5       | 774          | 19.0       | 767          | 18.8       |
| 366-545 days                | 445          | 10.9       | 298          | 7.3        | 523          | 13.0       | 432          | 10.6       |
| 546-730 days                | 306          | 7.5        | 143          | 3.5        | 334          | 8.2        | 254          | 6.2        |
| >730 days                   | 486          | 11.9       | 250          | 6.1        | 735          | 18.0       | 625          | 15.3       |
| Mean                        | 316          |            | 221          |            | 397          |            | 342          |            |
| Median                      | 183          |            | 119          |            | 244          |            | 187          |            |
| SD                          | 341.0        |            | 264.4        |            | 400.5        |            | 384.2        |            |
| Min                         | 1            |            | 1            |            | 1            |            | 1            |            |
| Max                         | 1,886        |            | 1,805        |            | 1,867        |            | 1,898        |            |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.

### 9.2.3 ILD Narrow Definition Outcome Events

Pulmonary outcome events were identified via diagnosis codes comprising the narrow definition of ILD. Hospital records with admission dates after the patient Index Date through the end of the follow-up period were examined to identify suspected outcomes. A total of 113 cases of suspected Narrow Definition ILD were identified in the *ILD Narrow Definition analysis dataset*, and 52 of those were confirmed by the IAP-ILD. Nearly half the confirmed events (23 cases) occurred in the amiodarone cohort, with the remaining 29 cases appearing in relatively equal numbers in the dronedarone, sotalol and flecainide cohorts (9, 10 and 10 cases, respectively). ([Table 18](#))

[Table 18](#) also provides distributions of patients with confirmed cases of Narrow Definition ILD according to demographic and medical characteristics. Caution should be exercised in interpreting the numbers in this table, as the very small values in most cells (i.e.,  $n < 5$ ) preclude conducting a meaningful comparison of these patients' characteristics.

**Table 18: Adjudication Results of Suspected ILD Narrow Definition Outcome Events within the Follow-up Period according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                                                  | <b>Dronedarone<br/>N=4,087</b> |          | <b>Amiodarone<br/>N=4,087</b> |          | <b>Sotalol<br/>N=4,087</b> |          | <b>Flecainide<br/>N=4,087</b> |          |
|------------------------------------------------------------------|--------------------------------|----------|-------------------------------|----------|----------------------------|----------|-------------------------------|----------|
| <b>Characteristics, N %</b>                                      | <b>N</b>                       | <b>%</b> | <b>N</b>                      | <b>%</b> | <b>N</b>                   | <b>%</b> | <b>N</b>                      | <b>%</b> |
| All Patients with Suspected Outcome Events                       | 24                             | 0.6      | 42                            | 1.0      | 27                         | 0.7      | 20                            | 0.5      |
| <b>Adjudication Determination</b>                                |                                |          |                               |          |                            |          |                               |          |
| Yes                                                              | 9                              | 37.5     | 23                            | 54.8     | 10                         | 37.0     | 10                            | 50.0     |
| No                                                               | 11                             | 45.8     | 16                            | 38.1     | 13                         | 48.1     | 9                             | 45.0     |
| Indeterminate                                                    | 4                              | 16.7     | 3                             | 7.1      | 4                          | 14.8     | 1                             | 5.0      |
| <b>Characteristics of Patients with Confirmed Outcome Events</b> |                                |          |                               |          |                            |          |                               |          |
| <b>Demographics</b>                                              |                                |          |                               |          |                            |          |                               |          |
| Age at cohort entry date, Mean(SD)                               | 69.9                           | 6.3      | 73.6                          | 7.5      | 75.6                       | 8.1      | 73.9                          | 5.7      |
| 18-39 years                                                      | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| 40-49 years                                                      | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| 50-59 years                                                      | 1                              | 11.1     | 2                             | 8.7      | 0                          | 0.0      | 0                             | 0.0      |
| 60-69 years                                                      | 3                              | 33.3     | 2                             | 8.7      | 3                          | 30.0     | 3                             | 30.0     |
| 70-79 years                                                      | 4                              | 44.4     | 13                            | 56.5     | 4                          | 40.0     | 6                             | 60.0     |
| 80+ years                                                        | 1                              | 11.1     | 6                             | 26.1     | 3                          | 30.0     | 1                             | 10.0     |
| Gender (female)                                                  | 8                              | 88.9     | 11                            | 47.8     | 5                          | 50.0     | 5                             | 50.0     |
| Race                                                             |                                |          |                               |          |                            |          |                               |          |
| White                                                            | 1                              | 11.1     | 6                             | 26.1     | 3                          | 30.0     | 3                             | 30.0     |
| Asian or Pacific Islander                                        | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| Black                                                            | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| American Indian/Alaskan Native                                   | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| Two races reported                                               | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| Other                                                            | 1                              | 11.1     | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| Unknown                                                          | 7                              | 77.8     | 17                            | 73.9     | 7                          | 70.0     | 7                             | 70.0     |
| <b>History of Disease</b>                                        |                                |          |                               |          |                            |          |                               |          |
| Deyo-Charlson Index, Mean (SD)                                   | 2.8                            | 1.6      | 1.7                           | 1.6      | 2.4                        | 1.6      | 1.9                           | 2.3      |
| Asthma                                                           | 0                              | 0.0      | 2                             | 8.7      | 0                          | 0.0      | 3                             | 30.0     |
| Bronchitis                                                       | 0                              | 0.0      | 1                             | 4.3      | 1                          | 10.0     | 0                             | 0.0      |
| Chronic Obstructive Pulmonary Disease                            | 3                              | 33.3     | 5                             | 21.7     | 3                          | 30.0     | 2                             | 20.0     |
| Connective Tissue Disease                                        | 1                              | 11.1     | 1                             | 4.3      | 3                          | 30.0     | 1                             | 10.0     |
| Exposure to Toxins                                               | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 1                             | 10.0     |
| Gastroesophageal Reflux Disease                                  | 5                              | 55.6     | 5                             | 21.7     | 5                          | 50.0     | 2                             | 20.0     |
| <b>History of Medication Use</b>                                 |                                |          |                               |          |                            |          |                               |          |
| Other Anti-arrhythmic Agents                                     | 9                              | 100      | 23                            | 100      | 10                         | 100      | 10                            | 100      |
| Agents assoc. w drug-induced pulmonary disease                   | 9                              | 100      | 23                            | 100      | 10                         | 100      | 10                            | 100      |
| Therapeutic Oxygen Treatment                                     | 0                              | 0.0      | 0                             | 0.0      | 0                          | 0.0      | 0                             | 0.0      |
| <b>Outcome Latency from Index Date</b>                           |                                |          |                               |          |                            |          |                               |          |
| Up to 1 month                                                    | 1                              | 11.1     | 1                             | 4.3      | 0                          | 0.0      | 1                             | 10.0     |
| 1 Month to 6 months                                              | 2                              | 22.2     | 6                             | 26.1     | 0                          | 0.0      | 0                             | 0.0      |
| Greater than 6 months                                            | 6                              | 66.7     | 16                            | 69.6     | 10                         | 100      | 9                             | 90.0     |



Comparisons of incidence rates and hazard ratios for the ILD Narrow Definition primary analysis between each of the comparator cohorts versus the dronedarone cohort are found in **Table 19**. Total person-years of exposure for this analysis were calculated as the sum of person-years from Index Date through end of follow-up period for all patients in respective cohorts of the *ILD Narrow Definition analysis dataset*, with appropriate censoring applied to those cases with confirmed outcomes. Proportions of patients in each cohort remaining free of an ILD Narrow Definition outcome event for the same risk period are graphically displayed in a Kaplan-Meier graph (see **Figure 5**).

With more than double the number of confirmed events, the ILD Narrow Definition incidence rate in the amiodarone cohort was significantly higher than that of the dronedarone cohort (2.0 / 1,000 person-years of exposure versus 0.8 / 1,000 person-years of exposure,  $p=0.02$ ). The corresponding HR for this comparison was also significant (HR=2.5, 95% CI=1.1-5.3;  $p=0.02$ ). Incidence rates in the sotalol and flecainide cohorts were nearly identical to that of the dronedarone cohort (0.82 / 1,000 person-years of follow-up, 0.85/1,000 person-years of follow-up and 0.97 / 1,000 person-years of follow-up, respectively).

**Table 19: ILD Narrow Definition Analysis Dataset Incidence Rates (per 1,000 Person-Years of Follow-up) and Hazard Ratios of Confirmed Interstitial Lung Disease Events Identified during Follow-up Period: DOD Database - 20 July 2009 to 30 September 2014**

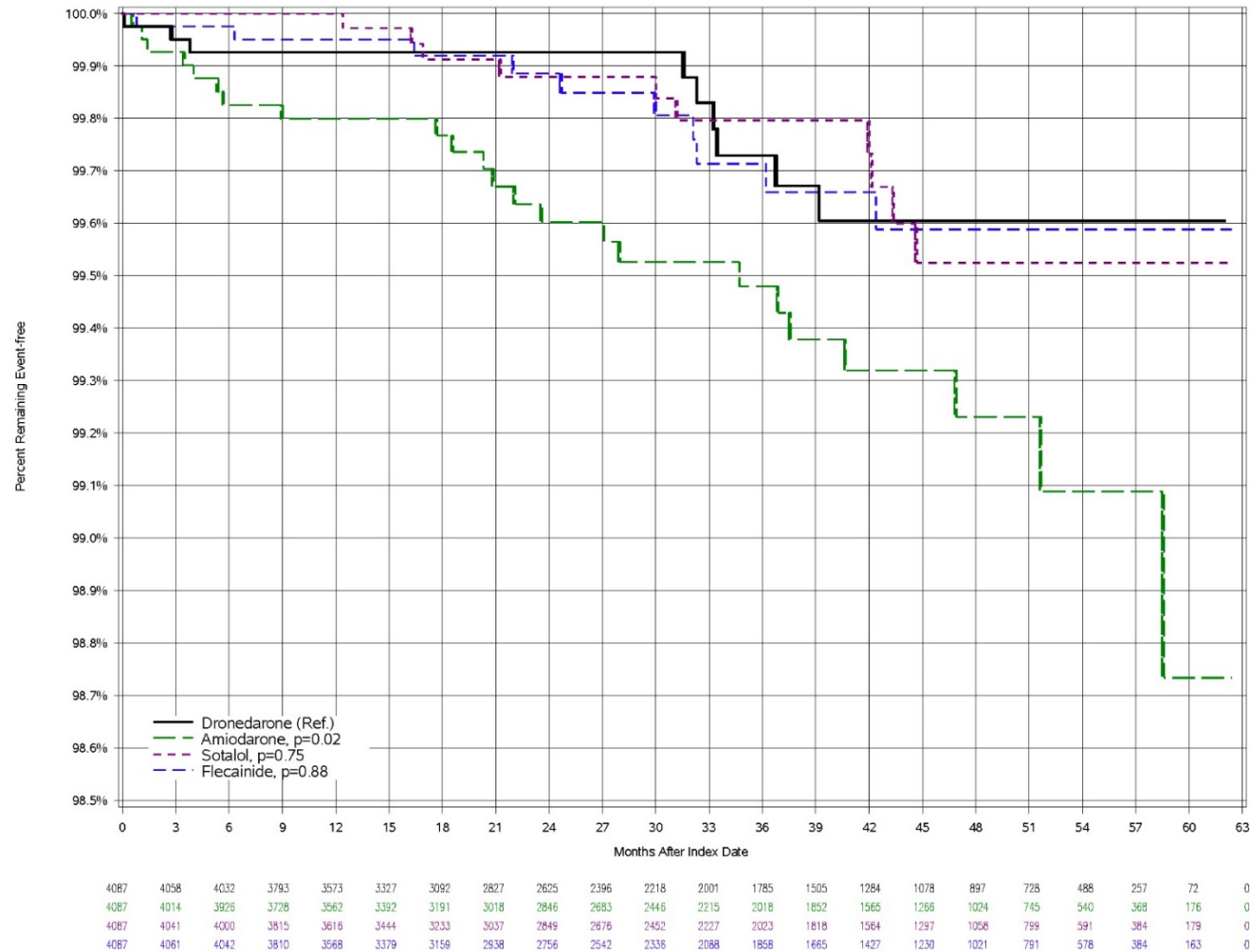
|                                            | <b>Dronedarone<br/>N=4,087</b> | <b>Amiodarone<br/>N=4,087</b> | <b>Sotalol<br/>N=4,087</b> | <b>Flecainide<br/>N=4,087</b> |
|--------------------------------------------|--------------------------------|-------------------------------|----------------------------|-------------------------------|
| <b>Cases adjudicated as Yes</b>            |                                |                               |                            |                               |
| Cases during follow-up period <sup>a</sup> | 9                              | 23                            | 10                         | 10                            |
| Person-Years of follow-up <sup>b</sup>     | 11,024.7                       | 11,649.6                      | 11,790.5                   | 11,466.4                      |
| Incidence rate (95% CI)                    | 0.82 (0.37-1.55)               | 1.97 (1.25-2.96)              | 0.85 (0.41-1.56)           | 0.87 (0.42-1.60)              |
| p-value IR difference from Dronedarone     | --                             | 0.02                          | 0.99                       | 0.88                          |
| Hazard Ratio (95%CI) <sup>c</sup>          | Reference                      | 2.5 (1.1-5.3)                 | 0.9 (0.3-2.1)              | 1.1 (0.4-2.6)                 |
| p-value of Hazard Ratio                    | --                             | 0.02                          | 0.75                       | 0.88                          |

<sup>a</sup> The follow-up period (ILD Risk Period 1) begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>b</sup> Person-years of follow-up is the sum of total days in ILD Risk Period 1 for all patients in the ILD Narrow Definition analysis dataset.

<sup>c</sup> Hazard ratio for dronedarone-flecainide comparison is a crude rate. Hazard ratio for dronedarone-amiodarone comparison is adjusted for study year of Index Date. Hazard ratio for dronedarone-sotalol comparison is adjusted for age on Index Date.

**Figure 5. ILD Narrow Definition Outcome Kaplan Meier Curve: Percent of Patients Remaining Event Free through End of Follow-up Period, ILD Narrow Definition Analysis Dataset**



### 9.3 OTHER ANALYSES

As only two SLD cases with the required laboratory data were identified in the SLD analysis dataset, the representativeness of those cases could not be assessed.

Three sensitivity analyses were conducted for the ILD outcome in order to address complexities of definition and outcome latency associated with ILD. Those separate analyses varied from the primary ILD analysis of this study by changing the definition of ILD used for baseline screening and outcome identification, and/or the risk period examined for ILD outcomes. Results of those sensitivity analyses are provided in [Appendix 13](#).

### 9.4 MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ ADVERSE REACTIONS

This study was based on the secondary use of data; expedited reporting of AE/ADR is not required.

## 10. DISCUSSION

### 10.1 KEY RESULTS

This study took advantage of the availability in the electronic medical records of the US DoD Military Health System of very large populations of patients treated for atrial fibrillation to compare the rate of occurrence of two key suspected adverse events of concern: serious liver disease (SLD) and interstitial lung disease (ILD) associated with dronedarone (where possible signals of these events were noted). Dronedarone users were compared with users of amiodarone, dofetilide, sotalol, propafenone, and flecainide. Due to insufficient numbers of patients exposed to allow appropriate statistical analysis, the latter two drugs were not included in the outcome analyses.

In these granular longitudinal datasets, the selected cohorts allowed extensive identification of pre- and post-exposure events, as well as propensity score matching to assure the cohorts were comparable as to risk factors. The patients were active participants in the Military Health System between 20 July 2008 and 30 September 2014 and were required to be  $\geq$  age 18 and have a first-time prescription for their anti-arrhythmic therapy between 20 July 2009 and 31 March 2014 for inclusion in the study population. In addition, they were required to have at least 365 days of continuous enrollment prior to and including the date of their index prescription fill, during which time a diagnosis of atrial fibrillation had to appear. Additional screening for the specific outcome study populations (SLD and ILD) were applied to remove patients who might have experienced the outcome prior to their Index Date. The resulting possible cases of SLD and ILD were carefully and independently evaluated by specialty

(hepatic and pulmonary) clinical adjudicators to determine the likelihood of being valid outcome events.

### SLD Findings

With respect to SLD, the proportion of patients with possible cases prior to propensity score matching was highest in the amiodarone cohort (0.4%, 97/22,908) compared to the other three cohorts included in the outcome analysis (0.2%, 18/8,821; 0.2%, 12/6,740; and 0.2%, 9/5,015 for the dronedarone, sotalol and flecainide cohorts, respectively) (**Table 1**). **Table 8** shows the numbers of SLD cases in the PS-matched cohorts that were provided to the adjudicators for review. The proportions of suspected SLD in each PS-matched cohort were similar to the proportions prior to PS matching (0.2%, 7/4,123; 0.3%, 13/4,123; 0.1%, 5/4,123; and 0.2%, 7/4,123 for the dronedarone, amiodarone, sotalol and flecainide cohorts, respectively). None were adjudicated as confirmed SLD (though one was Indeterminate); thus, no comparison could be conducted. Therefore the data do not suggest an increased risk of SLD among dronedarone users.

Although several differences existed in the disease and medication profiles of the SLD analysis cohorts, it is notable that relatively high proportions of patients in all cohorts were diabetic and were obese. As the details of these conditions were not explored in the scope of this study, there is no clear way to evaluate their impact on any of the suspect cases.

Similarly, although a number of cases were exposed to medications that can be “hepatotoxic,” this study did not further examine the precise relationship of exposure to those types of drugs and occurrence of the outcome events adjudicated. It is important to point out that most of these compounds (e.g., acetaminophen) are seldom hepatotoxic except when there is exposure to high doses (as in the case of acetaminophen) or in the case of the very rare idiosyncratic reaction.

### ILD Narrow Definition Findings

**Table 1** shows some variation by cohort in proportions of the study populations with suspected cases of narrow definition ILD prior to propensity score matching. Among the cohorts ultimately included in the primary ILD outcome analysis, the highest proportion of cases with suspected outcomes were found in the amiodarone cohort (1.05%, 194/18,521). The corresponding proportions of the dronedarone, sotalol and flecainide study populations were respectively 0.8% (66/8,128), 0.7% (41/6,140) and 0.4% (20/4,195). Numbers of suspected cases of Narrow Definition ILD in the PS-matched cohorts are reported in **Table 18**. Proportions of each PS-matched cohort with suspected Narrow Definition ILD were similar to those found in the corresponding groups prior to matching (0.6%, 24/4,087; 1.03%, 42/4,087; 0.7%, 27/4,087; and 0.5%, 20/4,087%, respectively for the dronedarone, amiodarone, sotalol and flecainide cohorts). **Table 19** summarizes the PS-matched data analyzed to show incidence rates by cohort and Hazard Ratios comparing the risk of ILD through the end of the follow-up period for each comparator versus dronedarone. That table shows that patients in

this population taking amiodarone, compared to the dronedarone patients, had a 2.5 times higher risk of an ILD outcome event over the course of the follow-up period (95% CI:1.1-5.3), as defined by the narrow definition.

Three sensitivity analyses variously combining a broader definition of ILD and / or shorter risk period did not show significant differences from results of the primary analysis (See [Appendix 12](#)).

## **Other Risk Factors**

### **Age**

Among patients meeting initial screening criteria of the *ILD Narrow Definition study population*, the amiodarone cohort had the oldest patients on average (mean age=73.2 years) and the flecainide cohort the youngest (63.7 years).

### **Medical Conditions**

Some concomitant conditions are associated with signs and symptoms that are shared with some of the disorders found in these patients. For example, a history of GERD was the most common of the six potentially related diseases examined for the ILD group, appearing in baseline records of more than one fourth the patients in all study drug cohorts. Some authors have identified GERD as one potential risk factor, if not cause of ILD.<sup>18</sup> Further, baseline COPD was found in as few as 9% of patients (in the relatively young flecainide group), and as many as 24% of patients (in the relatively oldest cohort of amiodarone users). In contrast to GERD, COPD does not result in the same complex of signs and symptoms that mimic ILD, so this is likely not a confounder.

### **Drugs**

Nearly all patients had filled at least one prescription for a drug potentially associated with pulmonary disease; however, as in the case of SLD, most of the drugs sometimes associated with pulmonary fibrosis are only very rarely associated with the ILD outcome. The occasional oncological /anti-rheumatic pharmaceuticals that are more commonly associated with ILD were only seen in a few patients in these data.

In summary, the primary findings were that based upon our analysis of very large populations we did not find significant differences in the rate of SLD in PS- matched cohorts. In contrast, the amiodarone cohort had a significantly higher incidence and risk over time of a confirmed ILD diagnosis than the dronedarone cohort. The ILD incidence rates for sotalol and flecainide cohorts were essentially the same as dronedarone.

## 10.2 LIMITATIONS

### Strengths

This study has a number of strengths, including electronic medical record longitudinal data on large populations of patients treated for atrial fibrillation. This provided the investigators with a very large number of lives and level of detail covered in the system, and allowed them to initially conduct overall surveillance of the population to assure adequate power in the ultimate epidemiological study.

A notable advantage of conducting this study in the DoD data is reduction of some biases inherent in other healthcare databases, such as socioeconomic disparities which are minimized due to a common employer and a strong rank structure. That structure provides for:

- A group of patients who have at least one family member who is fully employed or retired with benefits. In addition to the comprehensive pharmacy and medical benefits, the negligible unemployment ensures that financial considerations are minimized as a barrier to patient compliance.
- A correlation of social and economic class with military rank rather than race or gender, facilitating examination of the impact of those demographic characteristics separate from socioeconomic considerations.

Further, the population is representative of the US population overall.<sup>17</sup>

The study was reviewed by a Steering committee with diverse clinical expertise, as well as adjudication panel experts with longstanding experience in their respective specialties who contributed their experience to defining and assessing outcomes. The adjudication review, despite absence of some laboratory and diagnostic data, reflected the experts' careful consideration of all of the cases as evidenced by varied and detailed discussions in the adjudication meetings.

### Weaknesses

There were also several limitations in this study.

Although the DoD database afforded the investigators large amounts of data, these data nonetheless have limitations that affect the interpretation of results. Those included:

- Limited laboratory results data, which might have allowed for more precise adjudication of cases:
  - For SLD cases, the hepatologists found the absence of specific laboratory data rather limiting
  - For ILD cases, the lack of results of pulmonary function tests as well as lung scan results likewise were limiting
- Limited data on / difficult to ascertain smoking status

- Possible underreporting of some conditions (e.g., obesity, alcoholism, smoking) which may be relevant to outcomes
- Insufficient patients to include dofetilide and propafenone in the outcome analyses
- The fact that patients were primarily white, by race.

In addition, although SLD events have been reported to occur in association with the anti-arrhythmic drugs included in this study, since no cases were detected it is possible the cohorts were not large enough to detect actual cases of SLD, or that other features of cohort selection may have been factors in this finding. This may be a result of differences between this study and the earlier internal Sanofi study used as background to estimate the study's required sample size. The current study likely used more broadly inclusive definitions of SLD and ILD, while restricting outcomes to those that occurred in hospital or skilled nursing facilities. The longer baseline period (365 days in this study versus six months in the previous study) also meant that more patients with pre-existing conditions were screened out of the current analyses.

Finally, upon reviewing the individual cases there were often one or more concomitant conditions that were associated with SLD or ILD, respectively. For example, several SLD profiles included patients with recurrent congestive right heart failure that might have manifest as chronic passive hepatic congestion; similarly, a number of pulmonary cases also had sarcoidosis or multiple pulmonary conditions, and in many cases there were no pulmonary scans to allow clearer differentiation.

### **10.3 INTERPRETATION**

This study was undertaken in response to signals of SLD and ILD potentially associated with dronedarone.

With regard to SLD, this study provides no support for the signal. The finding of no confirmed cases of SLD suggests no increased risk of SLD with use of dronedarone versus the comparator anti-arrhythmics.

The study did find confirmed cases of ILD in all study drug cohorts. Incidence rate comparisons and survival analyses showed significantly higher rates of ILD, as well as risk through the follow-up period, among amiodarone than dronedarone users. These results, therefore, provide no evidence of increased risk of ILD associated with dronedarone use.

### **10.4 GENERALIZABILITY**

The DoD data have been shown to be representative of the broader US population.<sup>17</sup> As such, results of the study should be generalizable to US patients with similar demographic and medical characteristics.

## 11. OTHER INFORMATION

All information has been included in relevant report sections. There is no other information to report.

## 12. CONCLUSION

Results from this retrospective cohort study in a large EMR database show that the incidence of SLD and ILD in patients with AF treated with dronedarone are not different than in patients using most comparator drugs. Few SLD cases were identified, and none were adjudicated as confirmed SLD. Less than 1 case of ILD per 1,000 person-years was estimated in dronedarone users. Amiodarone was associated with an adjusted 2.5-fold higher risk of ILD than dronedarone with a point estimate of 2 cases per 1,000 person-years.

## 13. REFERENCES

1. Multaq® [package insert]. Bridgewater, NJ: Sanofi; 2014.
2. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022425s023lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022425s023lbl.pdf). Accessed February 1, 2017
3. Treatment Guidelines from the Medical Letter. 2010;8(97):65-70.
4. Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Heuzey J-Y L, Kay GN, Lowe SE, Olsson SB, Prystowsky EN, Tamargo JL, Wann, S. ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation—Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines: *Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society*. 2006 *Circulation*;114: 700-752.
5. Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Kay GN, Le Heuzey J-Y, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann LS. 2011 ACCF/AHA/HRS focused updates incorporated into the ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;123:e269–e367.
6. Lo Re V, Haynes K, Goldberg D, Forde KA, Carbonari DM, Leidl KBF, et al. Validity of diagnostic codes to identify cases of severe acute liver injury in the U.S. Food and Drug Administration's Mini-Sentinel Distributed Database. *Pharmacoepidemiol Drug Safe*. 2013;22:861-872.
7. Chan KA, Truman A, Gurwitz JH, Hurley JS, Martinson B, Platt R, Everhart JE, Moseley RH, Terrault N, Ackerson L, Selby JV. A cohort study of the incidence of serious acute liver injury in diabetic patients treated with hypoglycemic agents. *Arch Intern Med*. 2003 Mar 24;163(6):728-34.



8. Jones N, Schneider G, Kachroo S, Rotella P, Avetisyan R, Reynolds MW. A systematic review of validated methods for identifying pulmonary fibrosis and interstitial lung disease using administrative and claims data. *Pharmacoepidemiol Drug Safe*. 2012;21(S1):256-260.
9. <http://www.healthcommunities.com/liver-disease/causes.shtml>. Accessed May 17, 2013.
10. Schwaiblmair M, Behr W, Haeckel T, Märkl B, Foerg W, Berghaus T. Drug induced interstitial lung disease. *Open Respir Med J*. 2012;6:63-74. doi: 10.2174/1874306401206010063.
11. <http://www.mayoclinic.com/health/interstitial-lung-disease/DS00592/DSECTION=risk-factors>. Accessed May 17, 2013.
12. Hosmer, David W.; Lemeshow, Stanley (2000). *Applied Logistic Regression*. New York: Wiley. ISBN 0-471-61553-6.
13. Cox, D. R.; Oakes, D. (1984). *Analysis of Survival Data*. New York: Chapman & Hall.
14. Schoenfeld D. (1980). Chi-squared goodness-of-fit tests for the proportional hazards regression model. *Biometrika* **67**(1):145-153.
15. Kaplan, E. L.; Meier, P. (1958). "Nonparametric estimation from incomplete observations". *Journal of the American Statistical Association*. 53(282): 457–481.
16. Epstein M. Guidelines for Good Pharmacoepidemiology Practices (GPP). *Pharmacoepidemiol Drug Saf*. 2016;25:2-10.
17. Dorrance, K.A., Ramchandani, S., Neil, N., & Fisher, H. (2013). Leveraging the Military Health System as a Laboratory for Health Care Reform. *Military Medicine*, 178, 2:142.
18. Hershcovici T, Jha LK, Johnson T, Gerson L, et al. The Relationship Between Interstitial Lung Diseases and Gastro-oesophageal Reflux Disease. *Aliment Pharmacol Ther*. 2011;34(11):1295-1305.

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**APPENDIX 1. SURVEILLANCE OF DRONEDARONE USE AND  
OCCURRENCES OF SERIOUS LIVER  
INJURY/DISEASE AND INTERSTITIAL LUNG  
DISEASE OUTCOME EVENTS – STUDY REPORT**





# A SURVEILLANCE REPORT ON DRONEDARONE USE AND OCCURRENCES OF SERIOUS LIVER INJURY AND INTERSTITIAL LUNG DISEASE

STUDY REPORT

FOR  
SANOFI

Prepared by  
The Degge Group, Ltd.

2 March 2017

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## A Surveillance Report on Dronedarone Use and Occurrences of Serious Liver Injury/Disease and Interstitial Lung Disease

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## ABBREVIATIONS

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|                    |                                                                                           |
|--------------------|-------------------------------------------------------------------------------------------|
| ACE                | Angiotensin converting enzyme                                                             |
| AF                 | Atrial Fibrillation                                                                       |
| CHF                | Congestive heart failure                                                                  |
| CI                 | Confidence Interval                                                                       |
| COPD               | Chronic obstructive pulmonary disease                                                     |
| CPH                | Cox Proportional Hazard                                                                   |
| CPT®               | Current Procedural Terminology, American Medical Association                              |
| DCI                | Deyo-Charlson Index                                                                       |
| DEERS              | Defense Eligibility Enrollment Reporting System                                           |
| Degge              | The Degge Group, Ltd.                                                                     |
| DoD                | US Department of Defense, Military Health System Database                                 |
| DRG                | Diagnosis-Related Group                                                                   |
| EHR                | Electronic health record                                                                  |
| ESC                | Epidemiology Steering Committee                                                           |
| FDA                | U S Food and Drug Administration                                                          |
| GERD               | Gastroesophageal Reflux Disease                                                           |
| HCPSC              | Healthcare Common Procedure Coding System, Centers for Medicare & Medicaid Services       |
| HIRD <sup>sm</sup> | HealthCore Integrated Research Database                                                   |
| HIV                | Human Immunodeficiency Virus                                                              |
| HRTx               | Health ResearchTx, LLC                                                                    |
| IAC                | Independent Adjudication Committee                                                        |
| IAP                | Independent Adjudication Panel                                                            |
| ICD-9-CM           | International Classification of Diseases, 9 <sup>th</sup> Revision, Clinical Modification |
| ILD                | Interstitial lung disease                                                                 |
| MDR                | Military Health System Data Repository                                                    |
| MHS                | Military Health System                                                                    |
| NDC                | National Drug Code                                                                        |
| PDTS               | Pharmacy Data Transaction System                                                          |
| PS                 | propensity score                                                                          |
| PSM                | Propensity score matching                                                                 |
| SLD                | Serious liver injury/disease                                                              |

# **A Surveillance Report on Dronedarone Use and Occurrences of Serious Liver Injury/Disease and Interstitial Lung Disease**

For  
Sanofi

Prepared by  
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2 March 2017

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## **1. BACKGROUND**

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Dronedarone (Multaq®) is an anti-arrhythmic drug with effects from all four classes of the Vaughan Williams classification indicated for treatment of patients with non-permanent atrial fibrillation (AF).<sup>1</sup> The recommended dose is 400 mg twice daily in adults. Dronedarone was authorized on 1 July 2009 in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing analysis of spontaneous reports associated with dronedarone use identified safety signals related to serious liver injury/disease (SLD), and interstitial lung disease (ILD), which were also seen in association with the other treatments, notably amiodarone.<sup>2</sup> Two case reports that resulted in transplantation prompted the initiation of epidemiologic studies to examine dronedarone use and the occurrence of serious liver related injury.

As the first step toward an epidemiologic analysis, Sanofi contracted with The Degge Group Ltd. (Degge) to develop a comprehensive strategy for surveillance of a large proportion of the US population exposed to dronedarone. The goal of the surveillance was, to determine the feasibility of detecting, characterizing, and quantifying the occurrence of serious liver injury and interstitial lung disease associated with its use of dronedarone and other anti-arrhythmic drugs. Degge proposed a multi-dimensional program that utilized external data sources to meet these objectives.

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## 2. OBJECTIVES

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The primary and secondary objectives of the dronedarone surveillance study were:

- a. To count numbers of new users of dronedarone and comparator anti-arrhythmic drugs identified from administrative claims databases and electronic health records (EHR) on a quarterly basis. This systematic monitoring of databases representative of the general population would inform the timing at which a sufficiently powered formal epidemiologic study could be conducted.
- b. To identify the number of SLD and ILD occurrences among new users of dronedarone and comparator anti-arrhythmic drugs. Identification and profiling of SLD and ILD occurrences would inform the case definition of these events used in the formal epidemiologic study, and provide insight into the demographic and clinical profiles of patients associated with these cases.

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### 3. DATA SOURCES

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One electronic health record (EHR) system (US Department of Defense Military Health System Database), and one administrative claims database (HealthCore/HIRD) were identified as sources to monitor the use of dronedarone in the general population. Those two databases had the largest number of dronedarone users among three databases identified as potential sources. The database identified, but not selected for the surveillance activity, was I3/Ingenix Normative Health Information (NHI) Database.

#### 3.1 HEALTH RESEARCHTX / US DEPARTMENT OF DEFENSE (DOD)

Health ResearchTx (HRTX) is a health research organization that has a unique partnership with the United States Department of Defense (DoD) to leverage their Military Health System (MHS) Database to improve health outcomes, lower costs, and increase force readiness. The MHS provides health care for both active duty and retired military members and their families (beneficiaries).

As a single payer system, MHS provides uniform medical coverage and pharmacy benefits for more than 100 million covered lives. The database stores over 30 billion archived records, 5 billion online health records spanning more than 17 years, 260 years of ePrescribing and comparable decades of prescription, and includes both inpatient and outpatient data. Active duty members comprise approximately 17% of the MHS covered population. Records of veterans who receive medical coverage through the Veterans Administration are not captured in the DoD database.

The MHS provides two types of care to its beneficiaries. Direct care is provided through a network of military hospitals and clinics and while purchased care is delivered by civilian providers financed through managed care contracts and fee-for-service reimbursements. Direct care accounts for 37% of all care provided. All administrative events generated by either a direct care or purchased care encounter are tracked in the central MHS Data Repository (MDR). Examples of data recorded in the MDR include patient demographic data, provider information (provider ID, specialty, and facility), diagnostic codes (ICD-9-CM codes for outpatient visits; Diagnosis-Related Group (DRG) codes for inpatient stays) and Current Procedural Terminology (CPT®) codes for procedures. Extensive patient information including address, age, race, rank, and active duty status is also stored within the MDR via connections with the Defense Eligibility Enrollment Reporting System (DEERS). The DoD database also includes records from the military's electronic medication ordering system called the Pharmacy Data Transaction System (PDTS). PDTS includes electronically coded dispensing details of both direct care and purchased care outpatient medication orders, including the prescribed drug name and National Drug Code (NDC), dose, quantity, refills and prescribing provider.

### **3.2 HEALTHCORE / HIRD**

The HealthCore Integrated Research Database™ (HIRD) was monitored for new dronedarone users beginning on the product launch date. The HIRD represents a diverse spectrum of longitudinal claims data and the largest commercially-insured population in the United States (Southeastern, Mid-Atlantic, Northeastern, Central, and Western regions). It contains eligibility, medical, and pharmacy claims for more than 30 million fully-insured members. In addition, laboratory data are available for a subset of approximately 13+ million patients. Outpatient and inpatient clinical data contained in the HIRD are coded with International Classification of Disease (ICD) diagnosis and procedure codes, Code of Procedural Terminology (CPT) codes, and the Healthcare Common Procedure Coding System (HCPCS). Outpatient dispensing records are coded with National Drug Codes (NDCs) as well as by Generic Product Indicators (GPI), which include the drug name, dosage form and drug strength.

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## 4. METHODS

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### 4.1 Epidemiology Steering Committee

An Epidemiology Steering Committee (ESC) was convened to oversee the scientific integrity, validity of the study protocol, to assess of study quality and conduct, as well as, the scientific quality of interim reports and the final study report.

The ESC consisted of seven individuals. In addition, to the Committee Chair and Co-Chair, there were five individuals who were experts in one or more of the following areas: hepatology, cardiology, liver-associated injury, epidemiology, biostatistics, and regulatory drug safety.

#### Epidemiology Steering Committee Members

- Judith K Jones, MD, PhD, FISPE, **Chair**, *The Degge Group, Ltd., Fairfax, Virginia*
- Rhonda L Bohn, ScD, MPH, FISPE, **Co-Chair**, *Rhonda L Bohn, LLC, Boston, Massachusetts*
- Toby Barbey, MD, *Cardiologist, Social & Scientific Systems, Silver Spring, Maryland*
- Michael Gaziano, MD, MPH, *Cardiologist/Epidemiologist, Brigham & Women's Hospital, Boston, Massachusetts* [NOTE: Resigned 25 August 2014. A replacement was not identified.]
- James H. Lewis, MD, *Hepatologist, Georgetown University, Washington, District of Columbia*
- Captain Sally Tamayo, MD, *Cardiologist, Navy Medical Center, US Department of Defense, Portsmouth, Virginia*
- Susan T. Sacks, PhD, FISPE, *Epidemiologist/Statistician, Independent, Scottsdale, Arizona*

### 4.2 Study Design

A cohort design was employed to conduct the surveillance monitoring.

### 4.3 Study Period

The surveillance study period started on 20 July 2008. This provided a one-year screening period prior to the surveillance monitoring start date of 20 July 2009, the launch date for dronedarone. Monitoring continued through 31 March 2014 by which time sufficient numbers of dronedarone users were identified in the DoD and HIRD databases for the initiation of the pharmacoepidemiology study.

### 4.4 Study Populations

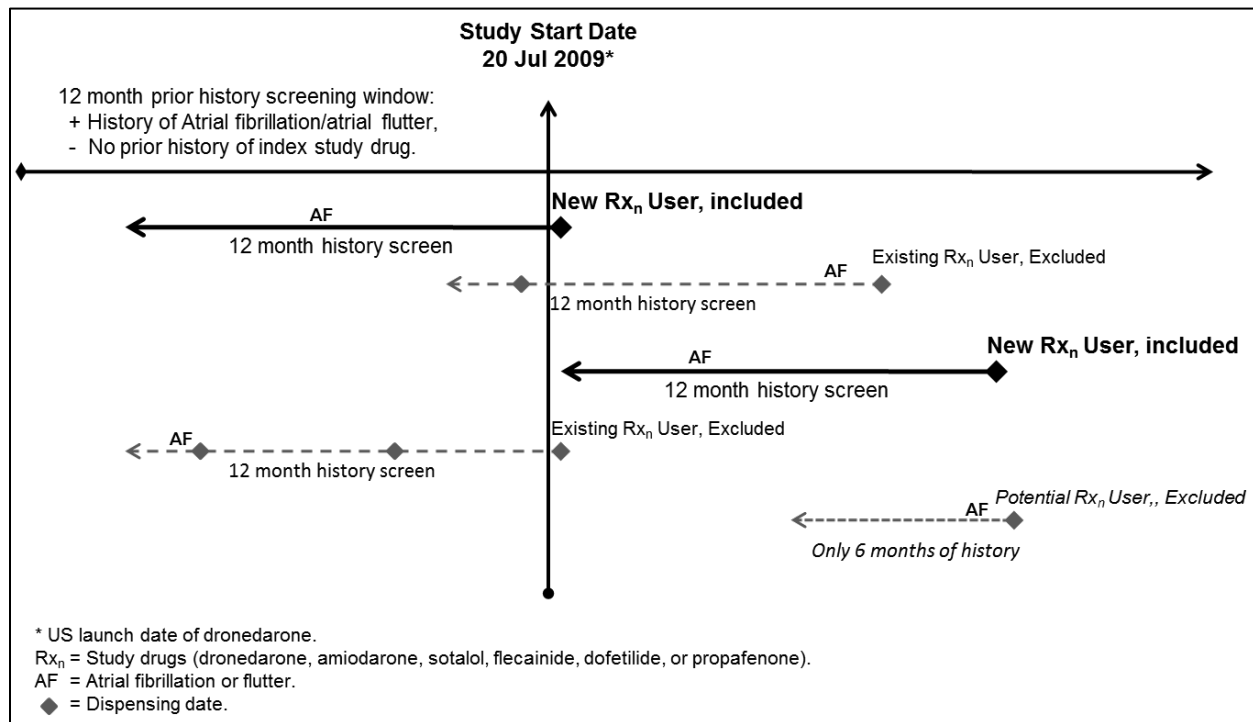
Study populations in the two databases included patients treated for newly occurring atrial fibrillation (AF) with either dronedarone or one of the specified comparator anti-arrhythmic drugs: amiodarone, sotalol, flecainide, dofetilide, or propafenone.<sup>3</sup> The comparator drugs were chosen as they are also used in the treatment of AF.



#### 4.4.1 Dronedarone Population

The two data sources concurrently identified patients who were new users of dronedarone via National Drug Codes (NDC (claims data)) or drug names (EHR system) starting from the date of product launch 20 July 2009. See [Appendix 1](#) for study population definitions. New users of dronedarone were required to have an AF diagnosis in the 12 months prior to the date of their first study drug fill (Index Date) and no use of dronedarone in the same 12-month period (baseline period). Baseline use of study drugs other than dronedarone (i.e., one of the comparator drugs) during the baseline period were permitted. See [Figure 1](#).

**Figure 1. Study Population Selection**



#### 4.4.2 Drug Comparator Populations

New users of amiodarone, sotalol, flecainide, dofetilide, and propafenone were identified in each data source using the same criteria applied to the dronedarone population.

That is, new users, of each comparator drug were defined as having an AF diagnosis in their baseline period, and no claims (or dispensing record) for the same drug in the 12 months prior to the Index Date. Baseline fills of dronedarone or one of the other comparator study drugs during the baseline period were permitted.

Patients were removed from the study populations for the following occurrences:

- Less than 365 days of eligibility in the baseline period;

- No AF in the baseline period;
- Index study drug in the baseline period; and
- Date of death preceding their Index Date.

The following exclusionary screening was added during the 2013-Q2 reporting period. These were specific to the Epidemiology Study Protocol inclusion / exclusion criteria.

- Less than 18 years old on the Index Date;
- Cancer or organ transplant in the baseline period;
- HIV in the baseline period;
- Pregnancy codes 280 days prior/post index date.

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## 5. COHORT MONITORING

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For the surveillance, existing new users of dronedarone and comparator drugs (amiodarone, sotalol, flecainide, dofetilide, and propafenone) were identified in records dated between 20 July 2009 and 31 December 2011 (retrospective data count). National Drug Codes (NDCs) were used to identify study drugs in the HIRD database, and dispensing data / NDC codes identified the study drugs in the DoD database.

Beginning 1 January 2012, new users of the study drugs of interest were identified prospectively in each data source (DoD, HIRD) at quarterly intervals. During the prospective monitoring period only new unique patients starting a study drug of interest in each quarter were added to the cumulative count. Evidence of a diagnosis of AF in the 12-month baseline was required in all cases.

Cumulative numbers of new users of each study drug were tabulated as study drug cohorts in each database. Patients were followed as members of their index study drug cohort until any of the following occurred:

- Discontinued a study drug of interest;
- Switched to another study drug of interest;
- Were no longer eligible members in the health plans under study;
- Occurrence of a serious liver injury/disease outcome occurrence / interstitial lung disease outcome occurrence; or
- Patient died.

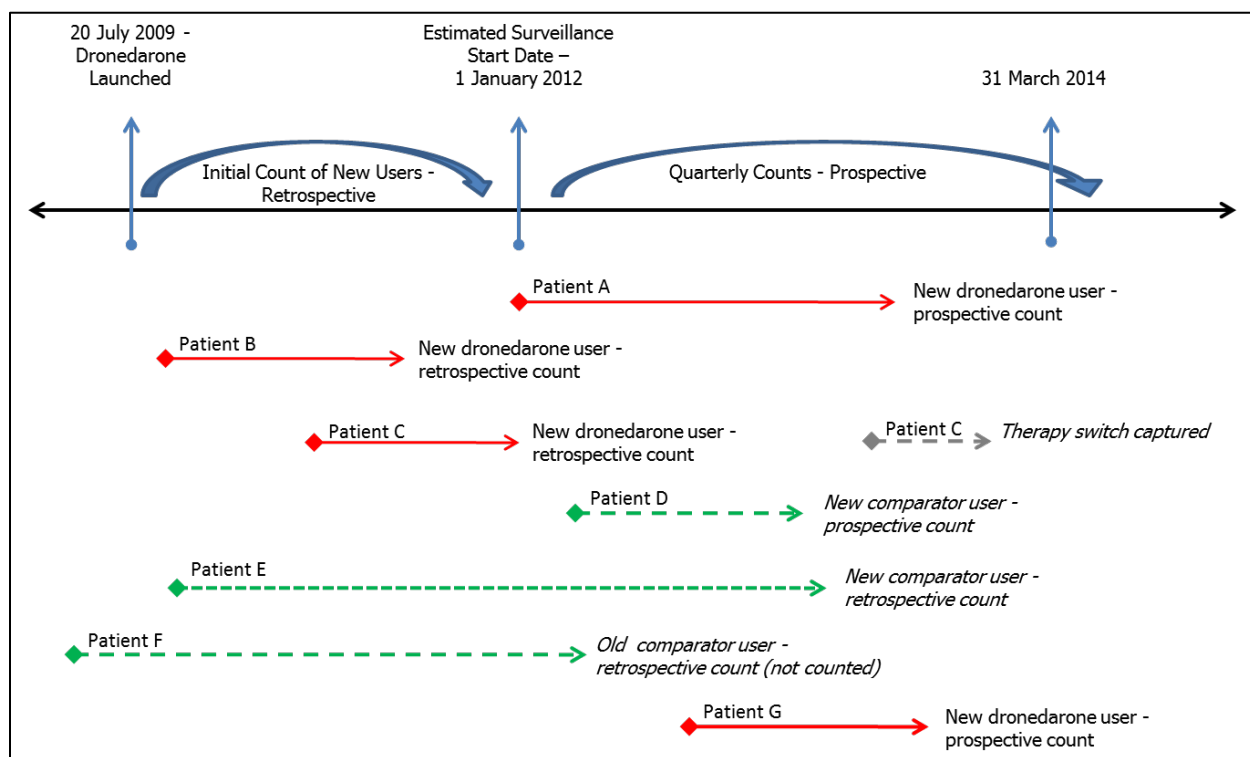
For all of the instances above (except for loss of eligibility and death), new study drug users were followed until the end of the study monitoring period.

Study drug discontinuation was defined as having no subsequent dispensing records for the index medication starting from the index prescription dispensed date plus the days supply value plus 60 days to account for potential non-adherence and/or delays in medication refill patterns.

Switching was defined as a claim or dispensing record for another study drug either during or following the duration of continuous therapy with the index drug, regardless of whether or not there was another claim for the index study drug on a later date. The time at which a patient switched or added another study drug (augmentation) terminated that patient's time in that index drug cohort. As stated earlier, although participation in the study cohort was terminated, patients were followed, until the end of the study monitoring period.

The schematic below (**Figure 2**) illustrates cohort follow-up.

**Figure 2. Cohort follow-up diagram**



As illustrated above, two users of dronedarone would be identified in the initial retrospective count (Patient B, Patient C); Patient A and Patient G would be identified prospectively. Similarly, one study drug comparator patient (Patient E) would be identified during the initial patient counts and two additional comparator drug users (Patient C & D) would be identified during prospective surveillance. One study drug user (Patient F) would not be counted in the initial retrospective or prospective count since use started in the six months prior to the 20 July 2009 start date. Patient C would be counted twice; once for dronedarone and once for a comparator drug, since the comparator study drug start date is greater than 60 days after their last dronedarone claim date plus days supply value and there is no use of either drug in the 12 months prior to study drug use.

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## 6. OUTCOMES OF INTEREST – SURVEILLANCE DEFINITIONS

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There were two surveillance outcome events of interest:

- Serious liver injury/disease (SLD)
- Interstitial lung disease (ILD)

### 6.1 Serious Liver Injury/Disease (SLD) Surveillance Outcome Definition

The number of SLD outcome event occurrences was identified by individual diagnosis code or procedure code that met the study SLD definition specified in the protocol. Text descriptions, including diagnoses and procedures and database specific codes, as well as lab values, were used to identify occurrences of SLD in the two databases. The initial SLD definition was based on the OMOP Acute Liver Failure definition.<sup>4</sup> **Table 1** lists the initial SLD definition used for the surveillance program, which was designed to be maximally sensitive.

**Table 1. Initial SLD Surveillance Definition**

| ICD-9-CM Diagnosis  |                                                                |
|---------------------|----------------------------------------------------------------|
| 570                 | Acute and subacute necrosis of liver                           |
| 571.5               | Cirrhosis of liver without mention of alcohol                  |
| 572.2               | Hepatic coma                                                   |
| 572.4               | Hepatorenal syndrome                                           |
| 573.0               | Chronic passive congestion of liver                            |
| 573.3               | Hepatitis, unspecified                                         |
| 573.8               | Other specified disorders of liver                             |
| 573.9               | Unspecified disorder of liver                                  |
| 782.4               | Jaundice, unspecified                                          |
| 789.1               | Hepatomegaly                                                   |
| 790.4               | Nonspecific elevation of levels of transaminase or LDH         |
| 790.5               | Other or nonspecified abnormal serum levels                    |
| 791.4               | Biliuria                                                       |
| 794.8               | Nonspecific abnormal results of liver function test            |
| ICD-9-CM Procedures |                                                                |
| 50.11               | Closed (percutaneous) [needle] biopsy of liver                 |
| 50.12               | Open biopsy of liver                                           |
| 50.13               | Transjugular liver biopsy                                      |
| 50.14               | Laparoscopic liver biopsy                                      |
| 50.5                | Liver transplant                                               |
| 50.51               | Auxiliary liver transplant                                     |
| 50.59               | Other transplant of liver                                      |
| 50.91               | Percutaneous aspiration of liver                               |
| CPT Procedure Codes |                                                                |
| 47000               | Biopsy of liver, needle; percutaneous                          |
| 47001               | Biopsy of liver, needle; done at time of other major procedure |
| 47100               | Biopsy of liver, wedge                                         |
| 47135               | Liver allotransplantation; orthotopic, partial or whole,       |
| 47136               | Liver allotransplantation; heterotopic, partial or whole,      |
| 78205               | Liver imaging (SPECT);                                         |
| 78206               | Liver imaging (SPECT); with vascular flow                      |

Revisions to the SLD surveillance definition during the course of the surveillance program included:

The following diagnosis codes were added:

- 277.4 Disorder of bilirubin excretions
- 572.8 Other sequelae of chronic liver disease (added 23 October 2013)
- V42.7 Liver replaced by transplant (added 12 March 2013)

The following diagnosis codes were removed:

- 573.4 Hepatic infarction
- 789.1 Hepatomegaly
- 790.4 Nonspecific elevation of levels of transaminase or LDH
- 790.5 Other or nonspecified abnormal serum levels
- 791.4 Biliuria

The ESC approved all revisions. See [Appendix 2](#) for the final expanded SLD surveillance definition used for the Quarterly Reports.

During the initial retrospective period, as well as, each quarterly monitoring period, the number of SLD occurrences was tabulated. Only the first occurrence of an SLD diagnosis code that occurred after the patient's Index Date was counted, regardless of the number of different liver injury diagnosis codes recorded after follow-up.

The time period for identification of serious liver injury occurrence began the day after the Index Date and continued to the end of the monitoring period unless censored, and patients were continuously followed for up to five years or end of the study period.

## 6.2 Interstitial Lung Disease (ILD) Surveillance Outcome Definition

The number of ILD outcome event occurrences was identified by individual diagnosis codes that met the study ILD definition in the protocol. Text descriptions, including diagnoses and database specific codes, were used to identify occurrences of ILD in the two databases.

The number of ILD outcome event occurrences was identified by individual diagnosis codes that met the study ILD definition in the protocol. The initial ILD definition was provided by Wanju Dai, MD, PhD, mirrored the diagnosis codes described in a systemic review for the FDA's Mini-Sentinel Project by Natalie Jones et al.<sup>5</sup> **Table 2** lists the initial ILD definition used for the surveillance program, which was designed to be maximally sensitive.

The ILD surveillance definition was revised during the course of the surveillance program.

**Table 2. Initial ILD Surveillance Definition**

| Code Type | DESCRIPTION                                                  |
|-----------|--------------------------------------------------------------|
| 495.9     | Unspecified allergic alveolitis and pneumonitis              |
| 515       | Postinflammatory pulmonary fibrosis                          |
| 516.3     | Idiopathic fibrosing alveolitis                              |
| 516.8     | Other specified alveolar and parietoalveolar pneumonopathies |
| 516.9     | Unspecified alveolar and parietoalveolar pneumonopathy       |

The following diagnosis codes were added:

- 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP) – added 12 Mar 2013
- 516.31 Idiopathic pulmonary fibrosis (IPF) – added 12 Mar 2013
- 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP) – added 12 Mar 2013
- 516.33 Acute interstitial pneumonitis (AIP) – added 12 Mar 2013
- 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD) – added 12 Mar 2013
- 516.35 Idiopathic lymphoid interstitial pneumonia (LIP) – added 12 Mar 2013
- 516.36 Cryptogenic organizing pneumonia (COP) – added 12 Mar 2013
- 516.37 Desquamative interstitial pneumonia (DIP) – added 12 Mar 2013

The ESC approved all revisions. See [Appendix 3](#) for the final expanded ILD surveillance definition for the Quarterly Reports.

During the initial retrospective period, as well as, each quarterly monitoring period, the number of ILD occurrences was tabulated. Only the first occurrence of an ILD diagnosis code that occurred after the patient's Index Date was counted, regardless of the number of different ILD diagnosis codes after the start of follow-up.

### 6.3 Patient Profiling

Profiles were generated from patient records for approximately 50 SLD patients and 50 ILD patients from each database. Degge provided a template to HealthCore, illustrating the overall format layout, and identifying the data elements to be included in the profiles they generated. The Patient Profiles helped to inform the outcome event definitions to use in the targeted epidemiologic study, and provided insight into the demographic, clinical profile, and drug switching patterns in the surveillance study populations.

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## 7. STATISTICAL ANALYSIS

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### 7.1 Analytic Approach

The basis for the analysis of the monitoring component of this study was counts. The number of new users of dronedarone, amiodarone, sotalol, flecainide, dofetilide, and propafenone, and the number of new occurrences of SLD and ILD were tabulated during the initial retrospective portion, and for each quarterly interval in the prospective data collection. Individual database reports for the retrospective period report and the prospective quarterly reports for DoD and HIRD are provided in [Appendix 4](#) and [Appendix 5](#), respectively.

### 7.2 Building of Case Algorithms

Patient profiles generated for cases with a suspected SLD or a suspected ILD outcome event were each reviewed to help more clearly define study definition criteria for SLD and ILD outcome events. Included in the patient profiles were demographic and clinical variables, including diagnosis and procedure codes during outpatient visits and inpatient stays, outpatient drug use and, if available, laboratory and other clinical reports. They provided insight into co-morbid conditions and other factors that may be associated with the two outcome events of interest. Patient profile examples for SLD and ILD are provided in [Appendix 6](#).

### 7.3 Sample Size

Sample-size requirements for the analyses were estimated based on the following statistical design parameters and assumptions. They are based on the population size prior to propensity score matching.

- **Type of Analysis:** Comparison of event-free “survival” time between the dronedarone-exposed cohort and each comparator (reference) cohort, by means of the log-rank test, or Cox proportional-hazards regression
- **Alpha Level:** 0.05 ( $p \leq 0.05$  considered statistically significant)
- **Power:** 80% (80% chance of obtaining a significant result if a true difference in event-free survival between cohorts exists, and is of an important magnitude)
- **Effect Size of Importance:** Hazard Ratio = 3.0
- **Incidence Rate in the Comparator (Reference) Group:** 1 event/1,000 patient-years
- **Group size Ratio:** 1:1 (equal numbers of dronedarone and comparator subjects), consistent with 1:1 propensity-score matching
- **Accrual Interval:** 5 years (July 2009 through March 2014)
- **Follow-up Beyond Last Accrual:** 6 months (Index Dates ranged from July 2009 through March 2014)



**Table 3** shows the number of dronedarone subjects required to provide 80% power, at the 0.05 alpha level, to detect hazard ratios of 2.0, 3.0, and 4.0, for various values of the comparator (reference) group incidence rate:

**Table 3. Sample Size Calculation**

| Incidence Rate (Events / patient-years In the Comparator Group) | # of Subjects Needed in Each Cohort |              |        |
|-----------------------------------------------------------------|-------------------------------------|--------------|--------|
|                                                                 | HR=2.0                              | HR=3.0       | HR=4.0 |
| 0.01%/year (1 / 10,000 patient-years)                           | 108,947                             | 38,553       | 22,698 |
| 0.02%/year (1 / 5,000 patient-years)                            | 54,477                              | 19,278       | 11,351 |
| 0.05%/year (1 / 2,000 patient-years)                            | 21,800                              | 7,714        | 4,542  |
| 0.1%/year (1 / 1,000 patient-years)                             | 10,906                              | <b>3,860</b> | 2,273  |
| 0.2%/year (1 / 500 patient-years)                               | 5,460                               | 1,933        | 1,138  |
| 0.5%/year (1 / 200 patient-years)                               | 2,192                               | 776          | 457    |
| 1%/year (1 / 100 patient-years)                                 | 1,103                               | 391          | 231    |

[Software used to produce calculations: PS - Power and Sample Size Calculations, version 3.0, by W. D. Dupont and W. D. Plummer (Vanderbilt University).]

The incidence rate of 1 per 1,000 patient years was considered a sufficiently conservative estimate to use in the sample size calculations. Therefore, for a HR of 3.0, the minimum required sample size was 3,860 patients per study drug cohort.

The *dofetilide* and *propafenone* cohorts did not meet the required sample size of 3,860 patients. They were excluded prior to the propensity score matched process.

Background data to support the sample size and power calculations were provided by Sanofi from a retrospective cohort study conducted internally by Sanofi in 2011. That study used integrated medical and prescription claims data from the LabRx database (Safety Study Report – Dronedarone, SR33589, GPE Pharmacoepidemiology, August 2, 2011). That study found the following:

| Outcome Studied                              | Incidence Rate / 1,000 PYs |
|----------------------------------------------|----------------------------|
| Incidence of acute liver injury <sup>‡</sup> | 7.6 (0.9 - 14.2)           |
| Incidence of interstitial lung disease       | 21.9 (10.5 - 33.4)         |

<sup>‡</sup> Defined as a primary diagnosis of acute or sub-acute necrosis of liver, hepatic coma, toxic hepatitis, or liver transplant in hospital by ICD-9-CM and CPT codes.

It was determined at the ESC meeting on 30 September 2014 that the sample size requirement of 3,860 had been met in four of the six drug cohorts in both databases. There were sufficient patient numbers to initiate the Dronedarone Epidemiology Study.

Final patient numbers indicating sufficient sample size in the dronedarone, amiodarone, sotalol, flecainide study drug cohorts to move forward with the Epidemiology Study Protocol in both the DoD Database and HIRD Database are provided in **Table 4** and **Table 5**, respectively.

**Table 4. Final DoD Patient Counts Indicating Sufficient Sample Size to Begin Epidemiology Study; US DoD Database: 20 July 2009 to 31 March 2014**

| Baseline Exclusionary Screening Description                       | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|-------------------------------------------------------------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Assign the first study drug as the cohort*                        | 15,887       | 100         | 72,639        | 100         | 26,823       | 100         | 16,108       | 100.0       | 3,094      | 100         | 11,782       | 100         |
| Less patients without 365 days of eligibility in baseline period  | 233          | 1.5         | 748           | 1.0         | 735          | 2.7         | 652          | 4.0         | 90         | 2.9         | 302          | 2.6         |
| Less patients without AF in baseline period                       | 2,113        | 13.3        | 19,648        | 27.0        | 6,273        | 23.4        | 4,344        | 27.0        | 340        | 11.0        | 2,584        | 21.9        |
| Less patients with the index drug in baseline period              | 0            | 0.0         | 13,848        | 19.1        | 9,284        | 34.6        | 3,982        | 24.7        | 1,300      | 42.0        | 4,016        | 34.1        |
| Less patients with date of death preceding Index Date             | 4            | 0.03        | 10            | 0.01        | 4            | 0.01        | 2            | 0.01        | 0          | 0.0         | 1            | 0.01        |
| Less patients below 18 years old on Index Date*                   | 0            | 0.0         | 4             | 0.01        | 2            | 0.01        | 3            | 0.02        | 0          | 0.0         | 2            | 0.02        |
| Less patients with cancer or organ transplant in baseline period* | 4,118        | 25.9        | 13,452        | 18.5        | 3,209        | 12.0        | 1,771        | 11.0        | 415        | 13.4        | 1,348        | 11.4        |
| Less patients with HIV in baseline period*                        | 0            | 0.0         | 11            | 0.02        | 4            | 0.01        | 3            | 0.02        | 1          | 0.03        | 2            | 0.02        |
| Less pregnant women*                                              | 5            | 0.03        | 33            | 0.05        | 13           | 0.05        | 23           | 0.14        | 2          | 0.06        | 8            | 0.07        |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>9,414</b> | <b>59.3</b> | <b>24,885</b> | <b>34.3</b> | <b>7,299</b> | <b>27.2</b> | <b>5,328</b> | <b>33.1</b> | <b>946</b> | <b>30.6</b> | <b>3,519</b> | <b>29.9</b> |
|                                                                   |              |             |               |             |              |             |              |             |            |             |              |             |
| Serious Liver Injury/Disease (SLD)                                | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Remaining patients prior to screening for Outcome Cohorts         | 9,414        | 59.3        | 24,885        | 34.3        | 7,299        | 27.2        | 5,328        | 33.1        | 945        | 30.5        | <b>3,519</b> | <b>29.9</b> |
| Less patients with SLD exclusionary codes in baseline period†     | 593          | 3.7         | 1,977         | 2.7         | 559          | 2.1         | 313          | 1.9         | 87         | 2.8         | 190          | 1.6         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                     | <b>8,821</b> | <b>55.5</b> | <b>22,908</b> | <b>31.5</b> | <b>6,740</b> | <b>25.1</b> | <b>5,015</b> | <b>31.1</b> | <b>858</b> | <b>27.7</b> | <b>3,329</b> | <b>28.3</b> |
|                                                                   |              |             |               |             |              |             |              |             |            |             |              |             |
| Interstitial Lung Disease (ILD) Narrow                            | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             |
|                                                                   | #            | %           | #             | %           | #            | %           | #            | %           | #          | %           | #            | %           |
| Remaining patients prior to screening for Outcome Cohorts         | 9,414        | 59.3        | 24,885        | 34.3        | 7,299        | 27.2        | 5,328        | 33.1        | 945        | 30.5        | <b>3,519</b> | <b>29.9</b> |
| Less patients with ILD (Narrow) exclusionary codes in baseline‡   | 1,286        | 8.1         | 6,364         | 8.8         | 1,159        | 4.3         | 413          | 2.6         | 150        | 4.8         | 427          | 3.6         |
| <b>Study Cohorts for ILD (Narrow) Outcome Analysis</b>            | <b>8,128</b> | <b>51.2</b> | <b>18,521</b> | <b>25.5</b> | <b>6,140</b> | <b>22.9</b> | <b>4,915</b> | <b>30.5</b> | <b>795</b> | <b>25.7</b> | <b>3,092</b> | <b>26.2</b> |

\* Additional screening to reflect Epidemiology Study Protocol.

† Includes SLD, viral hepatitis, and hereditary conditions

‡ Includes ILD, pneumonia, and sarcoidosis

**Table 5. Final HIRD Patient Counts Indicating Sufficient Sample Size to Begin Epidemiology Study; HIRD Database: 20 July 2009 to 31 March 2014**

| Baseline Exclusionary Screening Description                                                                                                                                                                                                                                                                                                                                                                                   | <u>Dronedarone</u>        |             | <u>Amiodarone</u>        |             | <u>Sotalol</u>        |             | <u>Flecainide</u>        |             | <u>Dofetilide</u>        |             | <u>Propafenone</u>        |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------|--------------------------|-------------|-----------------------|-------------|--------------------------|-------------|--------------------------|-------------|---------------------------|-------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                               | N                         | %           | N                        | (%)         | N                     | (%)         | N                        | (%)         | N                        | (%)         | N                         | (%)         |
| Assign the first study drug as the cohort                                                                                                                                                                                                                                                                                                                                                                                     | 9,041                     | (100)       | 53,133                   | (100)       | 24,311                | (100)       | 19,110                   | (100)       | 3,179                    | (100)       | 12,203                    | (100)       |
| Less patients without 365 days of eligibility prior to index date                                                                                                                                                                                                                                                                                                                                                             | 2,700                     | (30)        | 13,069                   | (25)        | 7,827                 | (32)        | 6,375                    | (33)        | 1,152                    | (36)        | 3,781                     | (31)        |
| Less patients without AF in the year prior to index date                                                                                                                                                                                                                                                                                                                                                                      | 433                       | (5)         | 8,982                    | (17)        | 3,285                 | (14)        | 3,224                    | (17)        | 97                       | (3)         | 1,477                     | (12)        |
| Less patients with the index drug in the year prior to index date                                                                                                                                                                                                                                                                                                                                                             | 0                         | (0)         | 8,130                    | (15)        | 5,878                 | (24)        | 3,560                    | (19)        | 919                      | (29)        | 2,914                     | (24)        |
| Less patients with multiple study drugs on index date                                                                                                                                                                                                                                                                                                                                                                         | 3                         | (0)         | 12                       | (0)         | 8                     | (0)         | 3                        | (0)         | 1                        | (0)         | 7                         | (0)         |
| Less patients with date of death preceding index date                                                                                                                                                                                                                                                                                                                                                                         | 9                         | (0)         | 23                       | (0)         | 12                    | (0)         | 1                        | (0)         | 2                        | (0)         | 2                         | (0)         |
| Less patients below 18 years old on index date <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                   | 2                         | (0)         | 2                        | (0)         | 3                     | (0)         | 9                        | (0)         | 0                        | (0)         | 1                         | (0)         |
| Less patients with cancer in baseline period <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                     | 1,322                     | (15)        | 6,386                    | (12)        | 1,706                 | (7)         | 1,080                    | (6)         | 209                      | (7)         | 853                       | (7)         |
| Less patients with transplant in baseline period <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                 | 2                         | (0)         | 29                       | (0)         | 2                     | (0)         | 4                        | (0)         | 1                        | (0)         | 4                         | (0)         |
| Less patients with HIV in baseline period <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                        | 7                         | (0)         | 10                       | (0)         | 3                     | (0)         | 5                        | (0)         | 2                        | (0)         | 0                         | (0)         |
| Less patients with pregnancy codes prior and/or post index date <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                  | 1                         | (0)         | 15                       | (0)         | 8                     | (0)         | 13                       | (0)         | 3                        | (0)         | 2                         | (0)         |
| Remaining patients prior to screening for Outcome Cohorts                                                                                                                                                                                                                                                                                                                                                                     | 4,562                     | (50)        | 16,475                   | (31)        | 5,579                 | (23)        | 4,836                    | (25)        | 793                      | (25)        | 3,162                     | (26)        |
| <b>Serious Liver Injury/Disease (SLD) - Prior SLD Screening<sup>2</sup></b>                                                                                                                                                                                                                                                                                                                                                   | <b><u>Dronedarone</u></b> |             | <b><u>Amiodarone</u></b> |             | <b><u>Sotalol</u></b> |             | <b><u>Flecainide</u></b> |             | <b><u>Dofetilide</u></b> |             | <b><u>Propafenone</u></b> |             |
| Remaining patients prior to identifying outcome analysis cohorts                                                                                                                                                                                                                                                                                                                                                              | 4,562                     | (50)        | 16,475                   | (31)        | 5,579                 | (23)        | 4,836                    | (25)        | 793                      | (25)        | 3,162                     | (26)        |
| Less patients with SLD in baseline period                                                                                                                                                                                                                                                                                                                                                                                     | 192                       | (2)         | 1,063                    | (2)         | 259                   | (1)         | 146                      | (1)         | 31                       | (1)         | 117                       | (1)         |
| Less patients with viral hepatitis in baseline period                                                                                                                                                                                                                                                                                                                                                                         | 84                        | (1)         | 319                      | (1)         | 96                    | (0)         | 86                       | (0)         | 17                       | (1)         | 59                        | (0)         |
| Less patients with hereditary conditions in baseline period                                                                                                                                                                                                                                                                                                                                                                   | 13                        | (0)         | 45                       | (0)         | 8                     | (0)         | 9                        | (0)         | 2                        | (0)         | 9                         | (0)         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                                                                                                                                                                                                                                                                                                                                                                                 | <b>4,274</b>              | <b>(47)</b> | <b>15,048</b>            | <b>(28)</b> | <b>5,216</b>          | <b>(21)</b> | <b>4,595</b>             | <b>(24)</b> | <b>743</b>               | <b>(23)</b> | <b>2,977</b>              | <b>(24)</b> |
| <b>Interstitial Lung Disease (ILD) - Prior ILD Screening<sup>2</sup></b>                                                                                                                                                                                                                                                                                                                                                      | <b><u>Dronedarone</u></b> |             | <b><u>Amiodarone</u></b> |             | <b><u>Sotalol</u></b> |             | <b><u>Flecainide</u></b> |             | <b><u>Dofetilide</u></b> |             | <b><u>Propafenone</u></b> |             |
| Remaining patients prior to identifying outcome analysis cohorts                                                                                                                                                                                                                                                                                                                                                              | 4,562                     | (50)        | 16,475                   | (31)        | 5,579                 | (23)        | 4,836                    | (25)        | 793                      | (25)        | 3,162                     | (26)        |
| Less patients with ILD in baseline period                                                                                                                                                                                                                                                                                                                                                                                     | 122                       | (1)         | 601                      | (1)         | 175                   | (1)         | 71                       | (0)         | 33                       | (1)         | 57                        | (0)         |
| Less patients with pneumonia in baseline period                                                                                                                                                                                                                                                                                                                                                                               | 323                       | (12)        | 3,237                    | (6)         | 499                   | (2)         | 198                      | (1)         | 67                       | (2)         | 170                       | (1)         |
| Less patients with sarcoidosis in baseline period                                                                                                                                                                                                                                                                                                                                                                             | 17                        | (4)         | 22                       | (0)         | 11                    | (0)         | 11                       | (0)         | 7                        | (0)         | 6                         | (0)         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                                                                                                                                                                                                                                                                                                                                                                                 | <b>4,100</b>              | <b>(45)</b> | <b>12,615</b>            | <b>(24)</b> | <b>4,894</b>          | <b>(20)</b> | <b>4,556</b>             | <b>(24)</b> | <b>686</b>               | <b>(22)</b> | <b>2,929</b>              | <b>(24)</b> |
| 1. Among the HealthCore Integrated Research Database <sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. <sup>4</sup> The Epidemiology Study will be conducted using this patient population. Only the index study drug will be counted, therefore a patient is only counted once. |                           |             |                          |             |                       |             |                          |             |                          |             |                           |             |
| 2. Additional screening to reflect Epidemiology Study Protocol.                                                                                                                                                                                                                                                                                                                                                               |                           |             |                          |             |                       |             |                          |             |                          |             |                           |             |

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## **8. LIMITATIONS**

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This is primarily a monitoring effort as a preface to planning a formal epidemiologic study. The number of patients dispensed dronedarone or comparator medications, and the number of patients identified with an occurrence of SLD or ILD are not exact numbers; they were estimates for planning the epidemiologic study.

Administrative claims data lack specificity in some diagnostic codes. Patient profiles helped to more clearly define study definition criteria for SLD and ILD outcome events.

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## **9. QUALITY ASSURANCE**

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The study was conducted in accordance with Guidelines for Good Pharmacoepidemiology Practice established by the International Society of Pharmacoepidemiology and Therapeutic Risk Management.<sup>6</sup> The Degge Group, Ltd, its employees, and consultants followed and documented adherence to these guidelines.

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## 10. REFERENCES

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1. Multaq® [package insert]. Bridgewater, NJ: Sanofi; 2014.
2. Treatment Guidelines from the Medical Letter. 2010;8(97):65-70.
3. Wann LS et al. 2011 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Updating 2006 Guideline): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J AM Coll Cardiol*. 2011;57:223-242.
4. Racoosin J, Ryan P. (2011) Implications of Health Outcomes of Interest Definitions: Acute Liver Injury Case Study. Website: <http://omop.fnih.org/AcuteLiverInjury>. Accessed
5. Lo Re V, Haynes K, Goldberg D, Forde KA, Carbonari DM, Leidl KBF, et al. Validity of diagnostic codes to identify cases of severe acute liver injury in the U.S. Food and Drug Administration's Mini-Sentinel Distributed Database. *Pharmacoepidemiol Drug Safe*. 2013;22:861-872.
6. Chan KA, Truman A, Gurwitz JH, Hurley JS, Martinson B, Platt R, Everhart JE, Moseley RH, Terrault N, Ackerson L, Selby JV. A cohort study of the incidence of serious acute liver injury in diabetic patients treated with hypoglycemic agents. *Arch Intern Med*. 2003 Mar 24;163(6):728-34.
7. Jones N, Schneider G, Kachroo S, Rotella P, Avetisyan R, Reynolds MW. A systematic review of validated methods for identifying pulmonary fibrosis and interstitial lung disease using administrative and claims data. *Pharmacoepidemiol Drug Safe*. 2012;21(S1):256-260.
8. Epstein M. Guidelines for Good Pharmacoepidemiology Practices (GPP). *Pharmacoepidemiol Drug Saf*. 2016;25:2-10.



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## APPENDIX 1. STUDY POPULATION DEFINITIONS

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### 1) Dronedarone – Multaq

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00024414210 | MULTAQ      |
| 00024414218 | MULTAQ      |
| 00024414250 | MULTAQ      |
| 00024414260 | MULTAQ      |
| 21695092060 | MULTAQ      |
| 53360414200 | MULTAQ      |
| 54868308600 | MULTAQ      |

End.

## 2) Amiodarone – Cordarone, Cordarone IV, Pacerone

| NDC         | DESCRIPTION                        |
|-------------|------------------------------------|
| 00008081401 | CORDARONE IV                       |
| 00008418802 | CORDARONE                          |
| 00008418804 | CORDARONE                          |
| 00008418806 | CORDARONE                          |
| 00074434835 | AMIODARONE HCL                     |
| 00093913306 | AMIODARONE HCL                     |
| 00093913352 | AMIODARONE HCL                     |
| 00093913393 | AMIODARONE HCL                     |
| 00143987501 | AMIODARONE HCL INJECTION, SOLUTION |
| 00143987510 | AMIODARONE HYDROCHLORIDE           |
| 00185014405 | AMIODARONE HCL                     |
| 00185014409 | AMIODARONE HCL                     |
| 00185014460 | AMIODARONE HCL                     |
| 00185014490 | AMIODARONE HCL                     |
| 00245014001 | PACERONE                           |
| 00245014030 | PACERONE                           |
| 00245014401 | PACERONE                           |
| 00245014411 | PACERONE                           |
| 00245014430 | PACERONE                           |
| 00245014489 | PACERONE                           |
| 00245014501 | PACERONE                           |
| 00245014511 | PACERONE                           |
| 00245014515 | PACERONE                           |
| 00245014530 | PACERONE                           |
| 00245014589 | PACERONE                           |
| 00245014701 | PACERONE                           |
| 00245014715 | PACERONE                           |
| 00245014760 | PACERONE                           |
| 00245014789 | PACERONE                           |
| 00245014790 | PACERONE                           |
| 00409193302 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193303 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193401 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193411 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409434835 | AMIODARONE HYDROCHLORIDE           |
| 00409434849 | NOVAPLUS AMIODARONE HYDROCHLORIDE  |
| 00548138000 | AMIODARONE HCL INJECTION           |
| 00548138100 | AMIODARONE HCL INJECTION           |
| 00548338000 | AMIODARONE HCL                     |
| 00555091704 | AMIODARONE HCL                     |
| 00555091709 | AMIODARONE HCL                     |
| 00615454505 | AMIODARONE HCL TABLET              |
| 00615454531 | AMIODARONE HCL TABLET              |
| 00615454539 | AMIODARONE HCL TABLET              |



| <b>NDC</b>  | <b>DESCRIPTION</b>                 |
|-------------|------------------------------------|
| 00703133201 | AMIODARONE HCL                     |
| 00703133203 | AMIODARONE HYDROCHLORIDE           |
| 00703133501 | AMIODARONE HCL                     |
| 00703133601 | AMIODARONE HCL                     |
| 00781120305 | AMIODARONE HCL                     |
| 00781120360 | AMIODARONE HCL                     |
| 00781120392 | AMIODARONE HCL                     |
| 10019013101 | AMIODARONE HCL                     |
| 10019013301 | AMIODARONE HCL                     |
| 10019013302 | AMIODARONE HCL                     |
| 10019013304 | AMIODARONE HCL                     |
| 10019013313 | AMIODARONE HCL                     |
| 10019013319 | AMIODARONE HCL                     |
| 10019013389 | AMIODARONE HCL                     |
| 10139005003 | AMIODARONE HCL                     |
| 10139005009 | AMIODARONE HCL                     |
| 10139005010 | AMIODARONE HCL                     |
| 10139005011 | AMIODARONE HCL                     |
| 10139005028 | AMIODARONE HCL                     |
| 13107005605 | AMIODARONE HYDROCHLORIDE           |
| 13107005660 | AMIODARONE HYDROCHLORIDE           |
| 17236007560 | AMIODARONE HCL                     |
| 21695079630 | AMIODARONE HCL                     |
| 21695079660 | AMIODARONE HCL                     |
| 21695079690 | AMIODARONE HCL                     |
| 25021030266 | AMIODARONE HCL INJECTION, SOLUTION |
| 25021030273 | AMIODARONE HYDROCHLORIDE           |
| 35356000110 | AMIODARONE                         |
| 35356000190 | AMIODARONE HCL                     |
| 38245013325 | AMIODARONE HCL                     |
| 38245013355 | AMIODARONE HCL                     |
| 38245013368 | AMIODARONE HCL                     |
| 38779048605 | AMIODARONE HCL                     |
| 38779048608 | AMIODARONE HCL                     |
| 43066015010 | NEXTERONE                          |
| 43066015020 | NEXTERONE                          |
| 43066036020 | NEXERONE INJECTION, SOLUTION       |
| 47463001360 | AMIODARONE HCL                     |
| 49349015402 | AMIODARONE HCL TABLET              |
| 49884045802 | AMIODARONE HCL                     |
| 49884045804 | AMIODARONE HCL                     |
| 49884045805 | AMIODARONE HCL                     |
| 51079090601 | AMIODARONE HCL                     |
| 51079090617 | AMIODARONE HYDROCHLORIDE           |
| 51079090619 | AMIODARONE HYDROCHLORIDE           |

| <b>NDC</b>  | <b>DESCRIPTION</b>                              |
|-------------|-------------------------------------------------|
| 51079090620 | AMIODARONE HCL                                  |
| 51138049130 | AMIODARONE HCL                                  |
| 51672402503 | AMIODARONE HCL TABLET                           |
| 51672402504 | AMIODARONE HCL                                  |
| 51672405506 | AMIODARONE HCL TABLET                           |
| 51672405600 | AMIODARONE HCL TABLET                           |
| 51672405601 | AMIODARONE HCL TABLET                           |
| 51672405603 | AMIODARONE HCL TABLET                           |
| 51672405606 | AMIODARONE HCL TABLET                           |
| 51672405700 | AMIODARONE HCL                                  |
| 51672405706 | AMIODARONE HCL                                  |
| 51862015560 | AMIODARONE HCL TABLET                           |
| 51862015630 | AMIODARONE HCL TABLET                           |
| 51927376000 | AMIODARONE HYDROCHLORIDE                        |
| 52125099202 | AMIODARONE HCL TABLET                           |
| 52533010158 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52533010159 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584015303 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584034835 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 52584087501 | AMIODARONE HCL INJECTION                        |
| 53808106601 | AMIODARONE HCL TABLET                           |
| 54569176500 | CORDARONE                                       |
| 54569514000 | AMIODARONE HCL                                  |
| 54569514001 | AMIODARONE HCL                                  |
| 54569612900 | AMIODARONE HCL                                  |
| 54868461800 | AMIODARONE HCL                                  |
| 54868461801 | AMIODARONE HCL                                  |
| 54868461802 | AMIODARONE HCL                                  |
| 54868461803 | AMIODARONE HCL                                  |
| 54868518600 | PACERONE                                        |
| 54868572200 | AMIODARONE                                      |
| 55045286400 | AMIODARONE                                      |
| 55045286406 | AMIODARONE                                      |
| 55048001360 | AMIODARONE HCL                                  |
| 55154499600 | PACERONE                                        |
| 55154549200 | PACERONE                                        |
| 55154560600 | PACERONE                                        |
| 55390005701 | AMIODARONE HCL                                  |
| 55390005710 | AMIODARONE HCL                                  |
| 55390005810 | AMIODARONE HCL                                  |
| 55390009710 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 55390010501 | AMIODARONE HCL                                  |
| 55648073901 | AMIODARONE HCL INJECTION                        |
| 55648073902 | AMIODARONE HCL INJECTION                        |
| 55648073904 | AMIODARONE HCL INJECTION                        |

| <b>NDC</b>  | <b>DESCRIPTION</b>                              |
|-------------|-------------------------------------------------|
| 55648078001 | AMIODARONE HCL INJECTION                        |
| 55887079801 | AMIODARONE                                      |
| 55887079830 | AMIODARONE                                      |
| 55953021440 | AMIODARONE HCL                                  |
| 55953021441 | AMIODARONE HCL                                  |
| 55953021470 | AMIODARONE HCL                                  |
| 57315000901 | AMIODARONE HCL TABLET                           |
| 57315000902 | AMIODARONE HCL TABLET                           |
| 57315000904 | AMIODARONE HCL TABLET                           |
| 58016030400 | AMIODARONE                                      |
| 58016030430 | AMIODARONE                                      |
| 58016030460 | AMIODARONE                                      |
| 58016030490 | AMIODARONE                                      |
| 60429024705 | AMIODARONE HCL                                  |
| 60429024760 | AMIODARONE HCL                                  |
| 60505072200 | AMIODARONE HCL                                  |
| 60505072201 | AMIODARONE HCL                                  |
| 60505265800 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265803 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265806 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265808 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 61703024103 | AMIODARONE HCL                                  |
| 61786030931 | AMIODARONE HCL TABLET                           |
| 62086015303 | AMIODARONE HCL                                  |
| 63323061603 | AMIODARONE HYDROCHLORIDE                        |
| 63323061609 | AMIODARONE HYDROCHLORIDE                        |
| 63323061613 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 63739038710 | AMIODARONE HYDROCHLORIDE                        |
| 64679073901 | AMIODARONE HCL INJECTION                        |
| 64679073902 | AMIODARONE HCL INJECTION                        |
| 64679078001 | AMIODARONE HCL INJECTION                        |
| 65084045618 | PACERONE                                        |
| 65084045620 | PACERONE                                        |
| 65841063105 | AMIODARONE HCL TABLET                           |
| 65841063106 | AMIODARONE HCL TABLET                           |
| 65841063110 | AMIODARONE HCL TABLET                           |
| 65841063114 | AMIODARONE HCL TABLET                           |
| 65841063130 | AMIODARONE HCL TABLET                           |
| 67457015300 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 67457015303 | AMIODARONE HCL                                  |
| 67457015309 | AMIODARONE HYDROCHLORIDE                        |
| 67457015318 | AMIODARONE HYDROCHLORIDE                        |
| 67544017630 | AMIODARONE HCL                                  |
| 67544057030 | PACERONE                                        |
| 68084037101 | AMIODARONE HYDROCHLORIDE                        |

| <b>NDC</b>  | <b>DESCRIPTION</b>       |
|-------------|--------------------------|
| 68084037111 | AMIODARONE HCL           |
| 68382022705 | AMIODARONE HYDROCHLORIDE |
| 68382022706 | AMIODARONE HCL TABLET    |
| 68382022710 | AMIODARONE HCL TABLET    |
| 68382022714 | AMIODARONE HYDROCHLORIDE |
| 68382022730 | AMIODARONE HCL TABLET    |
| 68382022777 | AMIODARONE HCL TABLET    |
| 76237010830 | AMIODARONE HCL TABLET    |

### 3) Sotalol – Betapace, Betapace AF, Sorine, Sorine AF

| NDC         | DESCRIPTION    |
|-------------|----------------|
| 00093106001 | SOTALOL HCL    |
| 00093106101 | SOTALOL HCL    |
| 00093106201 | SOTALOL HCL    |
| 00093106301 | SOTALOL HCL    |
| 00093740106 | SOTALOL HCL AF |
| 00093740206 | SOTALOL HCL AF |
| 00093740306 | SOTALOL HCL AF |
| 00115271101 | SOTALOL HCL    |
| 00115271102 | SOTALOL HCL    |
| 00115271103 | SOTALOL HCL    |
| 00115272201 | SOTALOL HCL    |
| 00115272202 | SOTALOL HCL    |
| 00115272203 | SOTALOL HCL    |
| 00115273301 | SOTALOL HCL    |
| 00115273302 | SOTALOL HCL    |
| 00115273303 | SOTALOL HCL    |
| 00115274401 | SOTALOL HCL    |
| 00115274402 | SOTALOL HCL    |
| 00115274403 | SOTALOL HCL    |
| 00185017001 | SOTALOL HCL    |
| 00185017005 | SOTALOL HCL    |
| 00185017009 | SOTALOL HCL    |
| 00185017101 | SOTALOL HCL    |
| 00185017105 | SOTALOL HCL    |
| 00185017109 | SOTALOL HCL    |
| 00185017401 | SOTALOL HCL    |
| 00185017405 | SOTALOL HCL    |
| 00185017409 | SOTALOL HCL    |
| 00185017701 | SOTALOL HCL    |
| 00185017705 | SOTALOL HCL    |
| 00185017709 | SOTALOL HCL    |
| 00245001201 | SORINE         |
| 00245001211 | SORINE         |
| 00245001289 | SORINE         |
| 00245001301 | SORINE         |
| 00245001311 | SORINE         |
| 00245001389 | SORINE         |
| 00245001401 | SORINE         |
| 00245001411 | SORINE         |
| 00245001489 | SORINE         |
| 00245001501 | SORINE         |
| 00245001511 | SORINE         |
| 00245001589 | SORINE         |
| 00378030501 | SOTALOL HCL    |
| 00378031001 | SOTALOL HCL    |
| 00378031401 | SOTALOL HCL    |
| 00378512301 | SOTALOL HCL    |
| 00378512401 | SOTALOL HCL    |
| 00378512501 | SOTALOL HCL    |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00440836030 | SOTALOL HCL        |
| 00440836060 | SOTALOL HCL        |
| 00440836090 | SOTALOL HCL        |
| 00440836091 | SOTALOL HCL        |
| 00440836130 | SOTALOL HCL        |
| 00440836160 | SOTALOL HCL        |
| 00440836190 | SOTALOL HCL        |
| 00440836191 | SOTALOL HCL        |
| 00440836230 | SOTALOL HCL        |
| 00440836260 | SOTALOL HCL        |
| 00440836290 | SOTALOL HCL        |
| 00440836291 | SOTALOL HCL        |
| 00603576910 | SOTALOL HCL        |
| 00603576921 | SOTALOL HCL        |
| 00603576928 | SOTALOL HCL        |
| 00603576929 | SOTALOL HCL        |
| 00603576932 | SOTALOL HCL        |
| 00603577010 | SOTALOL HCL        |
| 00603577021 | SOTALOL HCL        |
| 00603577025 | SOTALOL HCL        |
| 00603577028 | SOTALOL HCL        |
| 00603577029 | SOTALOL HCL        |
| 00603577032 | SOTALOL HCL        |
| 00603577110 | SOTALOL HCL        |
| 00603577121 | SOTALOL HCL        |
| 00603577128 | SOTALOL HCL        |
| 00603577129 | SOTALOL HCL        |
| 00603577132 | SOTALOL HCL        |
| 00603577221 | SOTALOL HCL        |
| 00603577228 | SOTALOL HCL        |
| 00603577229 | SOTALOL HCL        |
| 00677170901 | SOTALOL HCL        |
| 00677170905 | SOTALOL HCL        |
| 00677170906 | SOTALOL HCL        |
| 00677170907 | SOTALOL HCL        |
| 00677171001 | SOTALOL HCL        |
| 00677171005 | SOTALOL HCL        |
| 00677171006 | SOTALOL HCL        |
| 00677171101 | SOTALOL HCL        |
| 00677171105 | SOTALOL HCL        |
| 00677171106 | SOTALOL HCL        |
| 00677171201 | SOTALOL HCL        |
| 00677171205 | SOTALOL HCL        |
| 00677171206 | SOTALOL HCL        |
| 00677171207 | SOTALOL HCL        |
| 00677189301 | SOTALOL HCL AF     |
| 00677189306 | SOTALOL HCL AF     |
| 00677189401 | SOTALOL HCL AF     |
| 00677189406 | SOTALOL HCL AF     |
| 00677189501 | SOTALOL HCL AF     |
| 00677189506 | SOTALOL HCL AF     |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 15330020801 | SOTALOL HCL        |
| 15330020901 | SOTALOL HCL        |
| 15330021001 | SOTALOL HCL        |
| 21695039730 | SOTALOL            |
| 24338053025 | SOTYLIZE SOLUTION  |
| 24338053048 | SOTYLIZE SOLUTION  |
| 35356093530 | SOTALOL HCL        |
| 35356093560 | SOTALOL HCL        |
| 35356093590 | SOTALOL HCL        |
| 35356096430 | SOTALOL HCL        |
| 35356096460 | SOTALOL HCL        |
| 35356096490 | SOTALOL HCL        |
| 42291076001 | SOTALOL HCL        |
| 42291076101 | SOTALOL HCL        |
| 42291076201 | SOTALOL HCL        |
| 43063013330 | SOTALOL HCL        |
| 47463077830 | SOTALOL HCL AF     |
| 47463077930 | SOTALOL HCL AF     |
| 49884058201 | SOTALOL HCL        |
| 49884058210 | SOTALOL HCL        |
| 49884058301 | SOTALOL HCL        |
| 49884058310 | SOTALOL HCL        |
| 49884058401 | SOTALOL HCL        |
| 49884058410 | SOTALOL HCL        |
| 49884058501 | SOTALOL HCL        |
| 49884058510 | SOTALOL HCL        |
| 50419010510 | BETAPACE           |
| 50419010511 | BETAPACE           |
| 50419010610 | BETAPACE           |
| 50419010611 | BETAPACE           |
| 50419010710 | BETAPACE           |
| 50419010711 | BETAPACE           |
| 50419010910 | BETAPACE           |
| 50419010911 | BETAPACE           |
| 50419011506 | BETAPACE AF        |
| 50419011511 | BETAPACE AF        |
| 50419011606 | BETAPACE AF        |
| 50419011611 | BETAPACE AF        |
| 50419011906 | BETAPACE AF        |
| 50419011911 | BETAPACE AF        |
| 51138056130 | SOTALOL HCL        |
| 51138056230 | SOTALOL HCL        |
| 51138056330 | SOTALOL HCL        |
| 51138056430 | SOTALOL HCL        |
| 52544065401 | SOTALOL HCL        |
| 52544065501 | SOTALOL HCL        |
| 52544065601 | SOTALOL HCL        |
| 52544066501 | SOTALOL HCL        |
| 53217001190 | SOTALOL HCL        |
| 53489028801 | SOTALOL HCL        |
| 53489028802 | SOTALOL HCL        |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 53489028803 | SOTALOL HCL        |
| 53489028805 | SOTALOL HCL        |
| 53489028810 | SOTALOL HCL        |
| 53489028901 | SOTALOL HCL        |
| 53489028902 | SOTALOL HCL        |
| 53489028903 | SOTALOL HCL        |
| 53489028905 | SOTALOL HCL        |
| 53489028910 | SOTALOL HCL        |
| 53489029001 | SOTALOL HCL        |
| 53489029002 | SOTALOL HCL        |
| 53489029003 | SOTALOL HCL        |
| 53489029005 | SOTALOL HCL        |
| 53489029010 | SOTALOL HCL        |
| 53489029101 | SOTALOL HCL        |
| 53489029102 | SOTALOL HCL        |
| 53489029103 | SOTALOL HCL        |
| 53489029105 | SOTALOL HCL        |
| 53489029110 | SOTALOL HCL        |
| 53489050301 | SOTALOL            |
| 53489050303 | SOTALOL            |
| 53489050305 | SOTALOL            |
| 53489050306 | SOTALOL            |
| 53489050307 | SOTALOL            |
| 53489050310 | SOTALOL            |
| 53489050401 | SOTALOL            |
| 53489050403 | SOTALOL            |
| 53489050405 | SOTALOL            |
| 53489050406 | SOTALOL            |
| 53489050407 | SOTALOL            |
| 53489050410 | SOTALOL            |
| 53489050501 | SOTALOL            |
| 53489050503 | SOTALOL            |
| 53489050505 | SOTALOL            |
| 53489050506 | SOTALOL            |
| 53489050507 | SOTALOL            |
| 53489050510 | SOTALOL            |
| 54569443400 | BETAPACE           |
| 54569443500 | BETAPACE           |
| 54868442300 | BETAPACE AF        |
| 54868442301 | BETAPACE AF        |
| 54868443500 | SOTALOL HCL        |
| 54868443501 | SOTALOL HCL        |
| 54868443502 | SOTALOL HCL        |
| 54868443503 | SOTALOL HCL        |
| 54868554900 | SOTALOL HCL        |
| 54868554901 | SOTALOL HCL        |
| 54868561400 | SOTALOL HCL        |
| 54868561401 | SOTALOL HCL AF     |
| 55045316000 | SOTALOL HCL        |
| 55048077830 | SOTALOL HCL AF     |
| 55048077930 | SOTALOL HCL AF     |



| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 57866903201 | SOTALOL HCL        |
| 57866903202 | SOTALOL HCL        |
| 57866903203 | SOTALOL HCL        |
| 57866903204 | SOTALOL HCL        |
| 57866903301 | SOTALOL HCL        |
| 57866903302 | SOTALOL HCL        |
| 57866903303 | SOTALOL HCL        |
| 57866903304 | SOTALOL HCL        |
| 57866903401 | SOTALOL HCL        |
| 57866903402 | SOTALOL HCL        |
| 57866903403 | SOTALOL HCL        |
| 57866903404 | SOTALOL HCL        |
| 58016018800 | SOTALOL HCL        |
| 58016018802 | SOTALOL HCL        |
| 58016018830 | SOTALOL HCL        |
| 58016018860 | SOTALOL HCL        |
| 58016018890 | SOTALOL HCL        |
| 60429039001 | SOTALOL HCL        |
| 60429039060 | SOTALOL HCL        |
| 60429039101 | SOTALOL HCL        |
| 60429039160 | SOTALOL HCL        |
| 60429039201 | SOTALOL HCL        |
| 60429039260 | SOTALOL HCL        |
| 60429074801 | SOTALOL HCL        |
| 60429074901 | SOTALOL HCL        |
| 60429075001 | SOTALOL HCL        |
| 60429075101 | SOTALOL HCL        |
| 60429094801 | SOTALOL HCL        |
| 60429094901 | SOTALOL HCL        |
| 60429095001 | SOTALOL HCL        |
| 60429095101 | SOTALOL HCL        |
| 60505008000 | SOTALOL HCL        |
| 60505008010 | SOTALOL HCL        |
| 60505008100 | SOTALOL HCL        |
| 60505008110 | SOTALOL HCL        |
| 60505008200 | SOTALOL HCL        |
| 60505008201 | SOTALOL HCL        |
| 60505015900 | SOTALOL HCL        |
| 60505022201 | SOTALOL HCL AF     |
| 60505022210 | SOTALOL HCL        |
| 60505022220 | SOTALOL HCL        |
| 60505022301 | SOTALOL HCL AF     |
| 60505022310 | SOTALOL HCL        |
| 60505022320 | SOTALOL HCL        |
| 60505022401 | SOTALOL HCL AF     |
| 60505022410 | SOTALOL HCL        |
| 60505022420 | SOTALOL HCL        |
| 62451010510 | SOTALOL HCL        |
| 62451010610 | SOTALOL HCL        |
| 62451010710 | SOTALOL HCL        |
| 62451010910 | SOTALOL HCL        |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 63629471910 | SOTALOL HCL        |
| 63629472010 | SOTALOL HCL        |
| 63629472020 | SOTALOL HCL        |
| 65162072510 | SOTALOL HCL        |
| 65162072710 | SOTALOL HCL        |
| 65162073110 | SOTALOL HCL        |
| 67457017610 | SOTALOL HCL        |
| 68084038701 | SOTALOL HCL        |
| 68084038711 | SOTALOL HCL        |
| 68084049701 | SOTALOL HCL        |
| 68084049711 | SOTALOL HCL        |
| 68084065401 | SOTALOL HCL        |
| 68084065411 | SOTALOL HCL        |
| 68115066100 | SOTALOL HCL        |
| 68151270290 | SOTALOL HCL        |

#### 4) Flecainide – Tambocor

| NDC         | DESCRIPTION        |
|-------------|--------------------|
| 00054001020 | FLECAINIDE ACETATE |
| 00054001021 | FLECAINIDE ACETATE |
| 00054001025 | FLECAINIDE ACETATE |
| 00054001120 | FLECAINIDE ACETATE |
| 00054001121 | FLECAINIDE ACETATE |
| 00054001125 | FLECAINIDE ACETATE |
| 00054001220 | FLECAINIDE ACETATE |
| 00054001221 | FLECAINIDE ACETATE |
| 00054001225 | FLECAINIDE ACETATE |
| 00089030510 | TAMBOCOR           |
| 00089030516 | TAMBOCOR           |
| 00089030710 | TAMBOCOR           |
| 00089030716 | TAMBOCOR           |
| 00089031410 | TAMBOCOR           |
| 00089031416 | TAMBOCOR           |
| 00378850501 | FLECAINIDE ACETATE |
| 00378851001 | FLECAINIDE ACETATE |
| 00378851501 | FLECAINIDE ACETATE |
| 00440754260 | FLECAINIDE ACETATE |
| 00440754360 | FLECAINIDE ACETATE |
| 00440754460 | FLECAINIDE ACETATE |
| 00555085902 | FLECAINIDE ACETATE |
| 00555086002 | FLECAINIDE ACETATE |
| 00555086102 | FLECAINIDE ACETATE |
| 00781506201 | FLECAINIDE ACETATE |
| 00781506301 | FLECAINIDE ACETATE |
| 00781506401 | FLECAINIDE ACETATE |
| 12280018230 | TAMBOCOR           |
| 29336030510 | TAMBOCOR           |
| 29336030710 | TAMBOCOR           |
| 29336031410 | TAMBOCOR           |
| 29366031410 | TAMBOCOR           |
| 49884069401 | FLECAINIDE ACETATE |
| 49884069501 | FLECAINIDE ACETATE |
| 49884069601 | FLECAINIDE ACETATE |
| 50268032011 | FLECAINIDE ACETATE |
| 50268032015 | FLECAINIDE ACETATE |
| 50268032111 | FLECAINIDE ACETATE |
| 50268032115 | FLECAINIDE ACETATE |
| 50268032211 | FLECAINIDE ACETATE |
| 50268032215 | FLECAINIDE ACETATE |
| 51079098701 | FLECAINIDE ACETATE |
| 51079098720 | FLECAINIDE ACETATE |
| 51079098820 | FLECAINIDE ACETATE |
| 54569050000 | TAMBOCOR           |
| 54569613100 | FLECAINIDE ACETATE |
| 54569613200 | FLECAINIDE ACETATE |
| 54868440700 | TAMBOCOR           |
| 54868506500 | TAMBOCOR           |

| NDC         | DESCRIPTION        |
|-------------|--------------------|
| 54868506501 | TAMBOCOR           |
| 54868507400 | FLECAINIDE ACETATE |
| 54868507401 | FLECAINIDE ACETATE |
| 54868507402 | FLECAINIDE ACETATE |
| 54868507403 | FLECAINIDE ACETATE |
| 54868540500 | FLECAINIDE ACETATE |
| 54868540501 | FLECAINIDE ACETATE |
| 54868558600 | FLECAINIDE         |
| 54868558601 | FLECAINIDE ACETATE |
| 55045381901 | FLECAINIDE ACETATE |
| 58016096202 | FLECAINIDE ACETATE |
| 58016096203 | FLECAINIDE ACETATE |
| 58016096204 | FLECAINIDE ACETATE |
| 58016096230 | FLECAINIDE ACETATE |
| 58016096240 | FLECAINIDE ACETATE |
| 58016096256 | FLECAINIDE ACETATE |
| 58016096260 | FLECAINIDE ACETATE |
| 58016096290 | FLECAINIDE ACETATE |
| 60505266000 | FLECAINIDE ACETATE |
| 60505266001 | FLECAINIDE ACETATE |
| 60505266003 | FLECAINIDE ACETATE |
| 60505266005 | FLECAINIDE ACETATE |
| 60505266008 | FLECAINIDE ACETATE |
| 60505266100 | FLECAINIDE ACETATE |
| 60505266101 | FLECAINIDE ACETATE |
| 60505266103 | FLECAINIDE ACETATE |
| 60505266105 | FLECAINIDE ACETATE |
| 60505266108 | FLECAINIDE ACETATE |
| 60505266200 | FLECAINIDE ACETATE |
| 60505266201 | FLECAINIDE ACETATE |
| 60505266203 | FLECAINIDE ACETATE |
| 60505266205 | FLECAINIDE ACETATE |
| 63304079401 | FLECAINIDE ACETATE |
| 63304079501 | FLECAINIDE ACETATE |
| 63304079601 | FLECAINIDE ACETATE |
| 65162064110 | FLECAINIDE ACETATE |
| 65162064111 | FLECAINIDE ACETATE |
| 65162064210 | FLECAINIDE ACETATE |
| 65162064211 | FLECAINIDE ACETATE |
| 65162064310 | FLECAINIDE ACETATE |
| 65162064311 | FLECAINIDE ACETATE |
| 66105015202 | TAMBOCOR           |
| 66105015203 | TAMBOCOR           |
| 66105015206 | TAMBOCOR           |
| 66105015209 | TAMBOCOR           |
| 66105015210 | TAMBOCOR           |
| 68084054011 | FLECAINIDE ACETATE |
| 68084054021 | FLECAINIDE ACETATE |
| 68151146402 | FLECAINIDE ACETATE |
| 99207018050 | TAMBOCOR           |
| 99207018110 | TAMBOCOR           |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 99207018215 | TAMBOCOR           |

#### 5) Dofetilide – Tikosyn

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00069580043 | TIKOSYN     |
| 00069580060 | TIKOSYN     |
| 00069580061 | TIKOSYN     |
| 00069581043 | TIKOSYN     |
| 00069581060 | TIKOSYN     |
| 00069581061 | TIKOSYN     |
| 00069582043 | TIKOSYN     |
| 00069582060 | TIKOSYN     |
| 00069582061 | TIKOSYN     |

## 6) Propafenone – Rythmol, Rythmol SR

| NDC         | DESCRIPTION                   |
|-------------|-------------------------------|
| 00044502202 | RYTHMOL                       |
| 00044502210 | RYTHMOL                       |
| 00044502302 | RYTHMOL                       |
| 00044502310 | RYTHMOL                       |
| 00044502402 | RYTHMOL                       |
| 00044502410 | RYTHMOL                       |
| 00074162812 | RYTHMOL                       |
| 00074162814 | RYTHMOL                       |
| 00074173212 | RYTHMOL                       |
| 00074173214 | RYTHMOL                       |
| 00074183112 | RYTHMOL                       |
| 00074183114 | RYTHMOL                       |
| 00173078601 | RYTHMOL SR                    |
| 00173078801 | RYTHMOL SR                    |
| 00173078901 | RYTHMOL SR                    |
| 00173079220 | RYTHMOL                       |
| 00173079420 | RYTHMOL                       |
| 00173082318 | RYTHMOL SR                    |
| 00173082418 | RYTHMOL SR                    |
| 00173082618 | RYTHMOL SR                    |
| 00591058201 | PROPAFENONE HCL               |
| 00591058301 | PROPAFENONE HCL               |
| 00603544810 | PROPAFENONE, FILM COATED      |
| 00603544821 | PROPAFENONE HCL               |
| 00603544825 | PROPAFENONE HCL               |
| 00603544828 | PROPAFENONE, FILM COATED      |
| 00603544832 | PROPAFENONE, FILM COATED      |
| 00603544910 | PROPAFENONE, FILM COATED      |
| 00603544921 | PROPAFENONE HCL               |
| 00603544925 | PROPAFENONE, FILM COATED      |
| 00603544928 | PROPAFENONE, FILM COATED      |
| 00603544932 | PROPAFENONE, FILM COATED      |
| 00603545010 | PROPAFENONE, FILM COATED      |
| 00603545021 | PROPAFENONE HCL               |
| 00603545028 | PROPAFENONE, FILM COATED      |
| 00603545032 | PROPAFENONE, FILM COATED      |
| 00615757439 | PROPAFENONE, FILM COATED      |
| 00677181501 | PROPAFENONE HCL               |
| 00677181503 | PROPAFENONE HCL               |
| 00677181505 | PROPAFENONE HCL               |
| 00677181601 | PROPAFENONE HCL               |
| 00677181603 | PROPAFENONE HCL               |
| 00677181605 | PROPAFENONE HCL               |
| 00677181701 | PROPAFENONE HCL               |
| 00677181703 | PROPAFENONE HCL               |
| 00677181705 | PROPAFENONE HCL               |
| 05515509500 | PROPAFENONE, FILM COATED      |
| 21695081460 | PROPAFENONE HCL ER            |
| 49884009901 | PROPAFENONE, EXTENDED RELEASE |

| <b>NDC</b>  | <b>DESCRIPTION</b>            |
|-------------|-------------------------------|
| 49884009902 | PROPAFENONE HCL ER            |
| 49884009905 | PROPAFENONE HCL ER            |
| 49884009909 | PROPAFENONE HCL ER            |
| 49884009910 | PROPAFENONE, EXTENDED RELEASE |
| 49884011301 | PROPAFENONE, EXTENDED RELEASE |
| 49884011302 | PROPAFENONE, EXTENDED RELEASE |
| 49884011305 | PROPAFENONE, EXTENDED RELEASE |
| 49884011309 | PROPAFENONE, EXTENDED RELEASE |
| 49884011310 | PROPAFENONE, EXTENDED RELEASE |
| 49884020902 | PROPAFENONE HCL ER            |
| 49884020905 | PROPAFENONE HCL ER            |
| 49884020909 | PROPAFENONE HCL ER            |
| 49884021001 | PROPAFENONE, EXTENDED RELEASE |
| 49884021002 | PROPAFENONE HCL ER            |
| 49884021005 | PROPAFENONE HCL ER            |
| 49884021009 | PROPAFENONE HCL ER            |
| 49884021010 | PROPAFENONE, EXTENDED RELEASE |
| 49884021101 | PROPAFENONE, EXTENDED RELEASE |
| 49884021102 | PROPAFENONE HCL ER            |
| 49884021105 | PROPAFENONE HCL ER            |
| 49884021109 | PROPAFENONE HCL ER            |
| 49884021110 | PROPAFENONE, EXTENDED RELEASE |
| 50111070801 | PROPAFENONE HCL               |
| 50111070901 | PROPAFENONE HCL               |
| 50111071001 | PROPAFENONE HCL               |
| 51079099601 | PROPAFENONE HCL               |
| 51079099620 | PROPAFENONE HCL               |
| 52544058201 | PROPAFENONE HCL               |
| 52544058301 | PROPAFENONE HCL               |
| 53489055101 | PROPAFENONE HCL               |
| 53489055103 | PROPAFENONE HCL               |
| 53489055105 | PROPAFENONE HCL               |
| 53489055107 | PROPAFENONE, FILM COATED      |
| 53489055110 | PROPAFENONE, FILM COATED      |
| 53489055201 | PROPAFENONE HCL               |
| 53489055203 | PROPAFENONE HCL               |
| 53489055205 | PROPAFENONE HCL               |
| 53489055207 | PROPAFENONE, FILM COATED      |
| 53489055210 | PROPAFENONE, FILM COATED      |
| 53489055301 | PROPAFENONE HCL               |
| 53489055303 | PROPAFENONE HCL               |
| 53489055305 | PROPAFENONE HCL               |
| 53489055307 | PROPAFENONE, FILM COATED      |
| 53489055310 | PROPAFENONE, FILM COATED      |
| 54569613300 | PROPAFENONE HCL               |
| 54868477000 | PROPAFENONE HCL               |
| 54868477001 | PROPAFENONE HYDROCHLORIDE     |
| 54868477002 | PROPAFENONE HYDROCHLORIDE     |
| 54868477003 | PROPAFENONE HCL               |
| 54868477004 | PROPAFENONE HYDROCHLORIDE     |
| 54868477005 | PROPAFENONE HYDROCHLORIDE     |



| <b>NDC</b>  | <b>DESCRIPTION</b>        |
|-------------|---------------------------|
| 54868595000 | PROPAFENONE HCL           |
| 54868595001 | PROPAFENONE HCL           |
| 54868595002 | PROPAFENONE, FILM COATED  |
| 58016030300 | PROPAFENONE               |
| 58016030330 | PROPAFENONE               |
| 58016030360 | PROPAFENONE               |
| 58016030390 | PROPAFENONE               |
| 58177033104 | PROPAFENONE HCL           |
| 58177033111 | PROPAFENONE HCL           |
| 58177033112 | PROPAFENONE HCL           |
| 58177033204 | PROPAFENONE HCL           |
| 58177033304 | PROPAFENONE HCL           |
| 62559023001 | PROPAFENONE, FILM COATED  |
| 62559023101 | PROPAFENONE, FILM COATED  |
| 62559023201 | PROPAFENONE, FILM COATED  |
| 63629386901 | PROPAFENONE HCL           |
| 63739050910 | PROPAFENONE, FILM COATED  |
| 63739051010 | PROPAFENONE, FILM COATED  |
| 65726026115 | RYTHMOL SR                |
| 65726026125 | RYTHMOL SR                |
| 65726026190 | RYTHMOL SR                |
| 65726026215 | RYTHMOL SR                |
| 65726026225 | RYTHMOL SR                |
| 65726026290 | RYTHMOL SR                |
| 65726026315 | RYTHMOL SR                |
| 65726026325 | RYTHMOL SR                |
| 65726026390 | RYTHMOL SR                |
| 65726026525 | RYTHMOL                   |
| 65726026590 | RYTHMOL                   |
| 65726026625 | RYTHMOL                   |
| 65726026690 | RYTHMOL                   |
| 65726026725 | RYTHMOL                   |
| 65726026790 | RYTHMOL                   |
| 66993011460 | PROPAFENONE SR            |
| 66993011560 | PROPAFENONE SR            |
| 66993011660 | PROPAFENONE SR            |
| 68084036101 | PROPAFENONE HYDROCHLORIDE |
| 68084036111 | PROPAFENONE HCL           |
| 68084085832 | PROPAFENONE ER            |
| 68084085833 | PROPAFENONE ER            |
| 68084091732 | PROPAFENONE ER            |
| 68084091733 | PROPAFENONE ER            |

## Atrial Fibrillation

| <b>ICD-9 CODE</b> | <b>Description</b>  |
|-------------------|---------------------|
| 427.31            | Atrial fibrillation |



## APPENDIX 2. SERIOUS LIVER INJURY/DISEASE DEFINITION

### Serious Liver Injury/Disease Codes:

| Code Type                  | DESCRIPTION                                                    |
|----------------------------|----------------------------------------------------------------|
| <b>ICD-9-CM Diagnoses</b>  |                                                                |
| 277.4*                     | Disorders of bilirubin excretion                               |
| 570                        | Acute and subacute necrosis of liver                           |
| 571.5                      | Cirrhosis of liver without mention of alcohol                  |
| 572.2                      | Hepatic coma                                                   |
| 572.4                      | Hepatorenal syndrome                                           |
| 572.8*                     | Other sequelae of chronic liver failure                        |
| 573.0                      | Chronic passive congestion of liver                            |
| 573.3                      | Hepatitis, unspecified                                         |
| 573.8                      | Other specified disorders of liver                             |
| 573.9                      | Unspecified disorder of liver                                  |
| 782.4                      | Jaundice, unspecified                                          |
| 794.8                      | Nonspecific abnormal results of liver function test            |
| V42.7*                     | Liver replaced by transplant                                   |
| <b>ICD-9-CM Procedures</b> |                                                                |
| 50.11                      | Closed (percutaneous) [needle] biopsy of liver                 |
| 50.12                      | Open biopsy of liver                                           |
| 50.13                      | Transjugular liver biopsy                                      |
| 50.14                      | Laparoscopic liver biopsy                                      |
| 50.5                       | Liver transplant                                               |
| 50.51                      | Auxiliary liver transplant                                     |
| 50.59                      | Other transplant of liver                                      |
| 50.91                      | Percutaneous aspiration of liver                               |
| <b>CPT Procedures</b>      |                                                                |
| 47000                      | Biopsy of liver, needle; percutaneous                          |
| 47001                      | Biopsy of liver, needle; done at time of other major procedure |
| 47100                      | Biopsy of liver, wedge                                         |
| 47135                      | Liver allotransplantation; orthotopic, partial or whole,       |
| 47136                      | Liver allotransplantation; heterotopic, partial or whole,      |
| 78205                      | Liver imaging (SPECT);                                         |
| 78206                      | Liver imaging (SPECT); with vascular flow                      |

The following codes were removed from the original definition:

- 573.4 Hepatic infarction
- 789.1 Hepatomegaly
- 790.4 Nonspecific elevation of levels of transaminase or LDH
- 790.5 Other or nonspecified abnormal serum levels
- 791.4 Biliuria

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## APPENDIX 3. INTERSTITIAL LUNG DISEASE DEFINITION

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### Interstitial Lung Disease (ILD)

| Code Type                 | DESCRIPTION                                                      |
|---------------------------|------------------------------------------------------------------|
| <b>ICD-9-CM Diagnoses</b> |                                                                  |
| 495.9                     | Unspecified allergic alveolitis and pneumonitis                  |
| 515                       | Postinflammatory pulmonary fibrosis                              |
| 516.3                     | Idiopathic fibrosing alveolitis                                  |
| 516.30*                   | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31*                   | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32*                   | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33*                   | Acute interstitial pneumonitis (AIP)                             |
| 516.34*                   | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35*                   | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36*                   | Cryptogenic organizing pneumonia (COP)                           |
| 516.37*                   | Desquamative interstitial pneumonia (DIP)                        |
| 516.8                     | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9                     | Unspecified alveolar and parietoalveolar pneumonopathy           |
| 518.82†                   | Acute respiratory distress syndrome                              |

\* Additional five digit diagnosis codes were approved by the ESC on 12 March 2013

† Acute respiratory distress syndrome code was approved on 30 September 2013

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## **APPENDIX 4. DOD DATABASE – QUARTERLY REPORTS OF PATIENT ACCRUALS**

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**Table 1. Numbers of patients by drug cohort, with numbers screened according to each screening criteria (only initial cohort in retrospective period)**

| <b>Patients Identified Jul 2009 - Dec 2011 (Retrospective Period)</b>                      | <b>Dronedarone</b> | <b>Amiodarone</b> | <b>Sotalol</b> | <b>Flecainide</b> | <b>Dofetilide</b> | <b>Propafenone</b> | <b>Total</b>  |
|--------------------------------------------------------------------------------------------|--------------------|-------------------|----------------|-------------------|-------------------|--------------------|---------------|
| Patients with each study drug between 7/20/09 and 12/31/11*                                | 16,639             | 51,091            | 22,261         | 12,081            | 3,209             | 10,200             | 115,481       |
| 1st study drug from 7/20/2009**                                                            | 10,769             | 47,018            | 20,319         | 10,740            | 2,288             | 9,054              | 100,188       |
| <i>Less patients without 365 days of eligibility prior the 1st study drug (index date)</i> | <i>140</i>         | <i>480</i>        | <i>445</i>     | <i>401</i>        | <i>50</i>         | <i>210</i>         | <i>1,726</i>  |
| Remaining patients                                                                         | 10,629             | 46,538            | 19,874         | 10,339            | 2,238             | 8,844              | 98,462        |
| <i>Less patients without AF in the year prior to index date</i>                            | <i>1,466</i>       | <i>12,604</i>     | <i>4,850</i>   | <i>2,947</i>      | <i>234</i>        | <i>2,065</i>       | <i>24,166</i> |
| Remaining patients                                                                         | 9,163              | 33,934            | 15,024         | 7,392             | 2,004             | 6,779              | 74,296        |
| <i>Less patients with the index study drug in the year prior to index date</i>             | <i>0</i>           | <i>13,976</i>     | <i>9,372</i>   | <i>4,020</i>      | <i>1,302</i>      | <i>4,037</i>       | <i>32,707</i> |
| Remaining patients                                                                         | 9,163              | 19,958            | 5,652          | 3,372             | 702               | 2,742              | 41,589        |
| <i>Less patients with multiple study drugs on index date</i>                               | <i>2</i>           | <i>18</i>         | <i>0</i>       | <i>2</i>          | <i>0</i>          | <i>3</i>           | <i>25</i>     |
| Remaining patients                                                                         | 9,161              | 19,940            | 5,652          | 3,370             | 702               | 2,739              | 41,564        |
| <i>Less patients with date of death preceding index date</i>                               | <i>2</i>           | <i>7</i>          | <i>3</i>       | <i>0</i>          | <i>0</i>          | <i>1</i>           | <i>13</i>     |
| <b>Retrospective Patient Cohort</b>                                                        | <b>9,159</b>       | <b>19,933</b>     | <b>5,649</b>   | <b>3,370</b>      | <b>702</b>        | <b>2,738</b>       | <b>41,551</b> |

\*Patients may be counted in more than one drug group

\*\* Patients are only counted once in their assigned index drug cohort

**Table 2. Overall Serious Liver Injury Disease Counts - July 20, 2009 - December 31, 2011, US DoD Military Health System<sup>1,2</sup>**

| Patients Identified Jul 2009 - Dec 2011 (Retrospective Period) | Dronedarone |            | Amiodarone   |            | Sotalol    |            | Flecainide |            | Dofetilide |            | Propafenone |            | Total        |            |
|----------------------------------------------------------------|-------------|------------|--------------|------------|------------|------------|------------|------------|------------|------------|-------------|------------|--------------|------------|
|                                                                | N           | %          | N            | %          | N          | %          | N          | %          | N          | %          | N           | %          | N            | %          |
|                                                                | 9,159       | 100.0      | 19,933       | 100.0      | 5,649      | 100.0      | 3,370      | 100.0      | 702        | 100.0      | 2,738       | 100.0      | 41,551       | 100.0      |
| <b>Serious Liver Injury*</b>                                   | <b>572</b>  | <b>6.2</b> | <b>1,518</b> | <b>7.6</b> | <b>337</b> | <b>6.0</b> | <b>152</b> | <b>4.5</b> | <b>39</b>  | <b>5.6</b> | <b>152</b>  | <b>5.6</b> | <b>2,770</b> | <b>6.7</b> |
| <b>ICD-9-CM Diagnosis</b>                                      |             |            |              |            |            |            |            |            |            |            |             |            |              |            |
| 570 Acute and Subacute Necrosis of Liver                       | 17          | 0.2        | 81           | 0.4        | 8          | 0.1        | 2          | 0.1        | 1          | 0.1        | 1           | 0.0        | 110          | 0.3        |
| 5715 Cirrhosis Of Liver without Mention of Alcohol             | 18          | 0.2        | 53           | 0.3        | 8          | 0.1        | 4          | 0.1        | 3          | 0.4        | 3           | 0.1        | 89           | 0.2        |
| 5722 Hepatic Coma                                              | 5           | 0.1        | 12           | 0.1        | 3          | 0.1        | 0          | 0.0        | 1          | 0.1        | 1           | 0.0        | 22           | 0.1        |
| 5724 Hepatorenal Syndrome                                      | 2           | 0.0        | 6            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 0           | 0.0        | 8            | 0.0        |
| 5730 Chronic Passive Congestion Of Liver                       | 3           | 0.0        | 19           | 0.1        | 2          | 0.0        | 0          | 0.0        | 0          | 0.0        | 2           | 0.1        | 26           | 0.1        |
| 5733 Hepatitis, Unspecified                                    | 18          | 0.2        | 73           | 0.4        | 10         | 0.2        | 6          | 0.2        | 2          | 0.3        | 7           | 0.3        | 116          | 0.3        |
| 5738 Other Specified Disorders of Liver                        | 127         | 1.4        | 286          | 1.4        | 96         | 1.7        | 40         | 1.2        | 4          | 0.6        | 35          | 1.3        | 588          | 1.4        |
| 5739 Unspecified Disorder of the Liver                         | 29          | 0.3        | 62           | 0.3        | 19         | 0.3        | 10         | 0.3        | 4          | 0.6        | 11          | 0.4        | 135          | 0.3        |
| 7824 Jaundice, Unspecified                                     | 26          | 0.3        | 61           | 0.3        | 14         | 0.2        | 5          | 0.1        | 1          | 0.1        | 6           | 0.2        | 113          | 0.3        |
| 7891 Hepatomegaly                                              | 35          | 0.4        | 80           | 0.4        | 14         | 0.2        | 11         | 0.3        | 0          | 0.0        | 10          | 0.4        | 150          | 0.4        |
| 7904 Nonspecific Elevation of Levels of Transaminase Or Ldh    | 95          | 1.0        | 256          | 1.3        | 58         | 1.0        | 29         | 0.9        | 10         | 1.4        | 23          | 0.8        | 471          | 1.1        |
| 7905 Other Or Nonspecified Abnormal Serum Levels               | 123         | 1.3        | 366          | 1.8        | 83         | 1.5        | 23         | 0.7        | 7          | 1.0        | 31          | 1.1        | 633          | 1.5        |
| 7914 Biluria                                                   | 1           | 0.0        | 2            | 0.0        | 1          | 0.0        | 0          | 0.0        | 1          | 0.1        | 1           | 0.0        | 6            | 0.0        |
| 7948 Nonspecific Abnormal Results of Liver Function Test       | 105         | 1.1        | 233          | 1.2        | 39         | 0.7        | 27         | 0.8        | 7          | 1.0        | 22          | 0.8        | 433          | 1.0        |
| <b>ICD-9-CM Procedures</b>                                     |             |            |              |            |            |            |            |            |            |            |             |            |              |            |
| 5011 Closed (Percutaneous) [needle] Biopsy of Liver            | 3           | 0.0        | 11           | 0.1        | 3          | 0.1        | 0          | 0.0        | 0          | 0.0        |             | 0.0        | 17           | 0.0        |
| 5012 Open Biopsy of Liver                                      | 0           | 0.0        | 0            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 1           | 0.0        | 1            | 0.0        |
| 5013 Transjugular Liver Biopsy                                 | 0           | 0.0        | 2            | 0.0        | 1          | 0.0        | 0          | 0.0        | 0          | 0.0        |             | 0.0        | 3            | 0.0        |
| 5014 Laparoscopic Liver Biopsy                                 | 2           | 0.0        | 0            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 1           | 0.0        | 3            | 0.0        |
| 5091 Percutaneous Aspiration of Liver                          | 0           | 0.0        | 3            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 1           | 0.0        | 4            | 0.0        |
| <b>CPT Procedures</b>                                          |             |            |              |            |            |            |            |            |            |            |             |            |              |            |
| 47000 Biopsy of Liver, Needle: Percutaneous                    | 3           | 0.0        | 13           | 0.1        | 2          | 0.0        | 0          | 0.0        | 0          | 0.0        | 2           | 0.1        | 20           | 0.0        |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other           | 1           | 0.0        | 2            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 0           | 0.0        | 3            | 0.0        |
| 47100 Biopsy of liver, wedge                                   | 0           | 0.0        | 1            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 0           | 0.0        | 1            | 0.0        |
| 78205 Liver Imaging (Spect)                                    | 0           | 0.0        | 1            | 0.0        | 0          | 0.0        | 0          | 0.0        | 0          | 0.0        | 1           | 0.0        | 2            | 0.0        |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all serious liver injury cases will be captured regardless of whether the

\*Liver injury diagnoses reported on date of first liver injury diagnosis after index date, for patients exiting liver injury monitoring cohort in this period due to liver injury diagnosis.

Note: Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the Overall Surveillance Study Medication Cohort patient count.



**Table 3. Overall Interstitial Lung Disease Counts - July 20, 2009 -December 31, 2011, US DoD Military Health System<sup>1,2</sup>**

| Patients Identified Jul 2009 - Dec 2011 (Retrospective Period)   | Dronedarone |            | Amiodarone |            | Sotalol    |            | Flecainide |            | Dofetilide |            | Propafenone |            | Total        |            |
|------------------------------------------------------------------|-------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|-------------|------------|--------------|------------|
|                                                                  | N           | %          | N          | %          | N          | %          | N          | %          | N          | %          | N           | %          | N            | %          |
|                                                                  | 9,159       | 100.0      | 19,933     | 100.0      | 5,649      | 100.0      | 3,370      | 100.0      | 702        | 100.0      | 2,738       | 100.0      | 41,551       | 100.0      |
| <b>Interstitial Lung Disease reported*</b>                       | <b>276</b>  | <b>3.0</b> | <b>849</b> | <b>4.3</b> | <b>166</b> | <b>2.9</b> | <b>66</b>  | <b>2.0</b> | <b>23</b>  | <b>3.3</b> | <b>77</b>   | <b>2.8</b> | <b>1,457</b> | <b>3.5</b> |
| 4959 Unspecified Allergic Alveolitis and Pneumonitis             | 2           | 0.0        | 8          | 0.0        | 1          | 0.0        | 0          | 0.0        | 0          | 0.0        | 1           | 0.0        | 12           | 0.0        |
| 515 Postinflammatory Pulmonary Fibrosis                          | 229         | 2.5        | 704        | 3.5        | 146        | 2.6        | 57         | 1.7        | 22         | 3.1        | 67          | 2.4        | 1,225        | 2.9        |
| 5163 Idiopathic Fibrosing Alveolitis                             | 18          | 0.2        | 43         | 0.2        | 7          | 0.1        | 2          | 0.1        | 0          | 0.0        | 3           | 0.1        | 73           | 0.2        |
| 5168 Other Specified Alveolar and Parietoalveolar Pneumonopathie | 9           | 0.1        | 38         | 0.2        | 5          | 0.1        | 5          | 0.1        | 1          | 0.1        | 1           | 0.0        | 59           | 0.1        |
| 5169 Unspecified Alveolar and Parietoalveolar Pneumonopathy      | 18          | 0.2        | 64         | 0.3        | 8          | 0.1        | 3          | 0.1        | 0          | 0.0        | 5           | 0.2        | 98           | 0.2        |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all serious liver injury cases will be captured regardless of whether the  
\*Lung disease diagnoses reported on date of first lung disease diagnosis after index date, for patients exiting lung disease monitoring cohort in this period due to lung disease diagnosis.

Note: Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the Overall Surveillance Study Medication Cohort patient count.



**Table 1. Number of Patients by Drug Cohort and Screening Criteria, US DoD Database: January to March 2012**

| Description                                                       | Dronedarone | Amiodarone   | Sotalol    | Flecainide | Dofetilide | Propafenone | Total        |
|-------------------------------------------------------------------|-------------|--------------|------------|------------|------------|-------------|--------------|
| Patients with a study drug between 1/1/2012 and 3/31/2012         | 7,363       | 20,146       | 12,687     | 7,082      | 2,011      | 5,261       | 53,653*      |
| Less patients already in previous surveillance dataset            | 4,469       | 6,515        | 3,424      | 2,009      | 736        | 1,335       | 18,148*      |
| Remaining patients                                                | 2,894       | 13,631       | 9,263      | 5,073      | 1,275      | 3,926       | 35,505*      |
| Assign the first study drug as the cohort                         | 2,789       | 13,430       | 9,160      | 5,009      | 1,246      | 3,871       | 35,505       |
| Less patients without 365 days of eligibility prior to index date | 35          | 95           | 187        | 116        | 27         | 62          | 522          |
| Remaining patients                                                | 2,754       | 13,335       | 8,973      | 4,893      | 1,219      | 3,809       | 34,983       |
| Less patients without AF in the year prior to index date          | 600         | 4,217        | 2,577      | 1,584      | 161        | 1,012       | 10,151       |
| Remaining patients                                                | 2,154       | 9,118        | 6,396      | 3,309      | 1,058      | 2,797       | 24,832       |
| Less patients with the index drug in the year prior to index date | 1,499       | 6,688        | 5,751      | 2,868      | 943        | 2,465       | 20,214       |
| Remaining patients                                                | 655         | 2,430        | 645        | 441        | 115        | 332         | 4,618        |
| Less patients with multiple study drugs on index date             | 1           | 0            | 0          | 0          | 0          | 0           | 1            |
| Remaining patients                                                | 654         | 2,430        | 645        | 441        | 115        | 332         | 4,617        |
| Less patients with date of death preceding index date             | 0           | 0            | 0          | 0          | 0          | 0           | 0            |
| <b>Patients in cohort</b>                                         | <b>654</b>  | <b>2,430</b> | <b>645</b> | <b>441</b> | <b>115</b> | <b>332</b>  | <b>4,617</b> |

\*Number of unique patients

Note: 690 of the 4,617 patients were also in the initial datasets used for the retrospective period.

542 patients out of 690 had a study drug from 7/20/2009, as required, but did not pass all the screening requirements and, thus, were not include

**Table 2. Serious Liver Injury Surveillance, US DoD Database: January to March 2012**

| US DoD Database Surveillance                                 | Dronedarone  |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide |              | Propafenone  |              | Identified in 2012Q1 |       | Cumulative Total |              |
|--------------------------------------------------------------|--------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|------------|--------------|--------------|--------------|----------------------|-------|------------------|--------------|
|                                                              | N            | %            | N             | %            | N            | %            | N            | %            | N          | %            | N            | %            | N                    | %     | N                | %            |
| <b>Total patients identified through 2012 Q1</b>             | <b>9,813</b> | <b>100.0</b> | <b>22,363</b> | <b>100.0</b> | <b>6,294</b> | <b>100.0</b> | <b>3,811</b> | <b>100.0</b> | <b>817</b> | <b>100.0</b> | <b>3,070</b> | <b>100.0</b> |                      |       | <b>46,168</b>    | <b>100.0</b> |
| <b>Patients identified prior to 2012 Q1</b>                  | 9,159        | 93.3         | 19,933        | 89.1         | 5,649        | 89.8         | 3,370        | 88.4         | 702        | 85.9         | 2,738        | 89.2         |                      |       | <b>41,551</b>    | <b>90.0</b>  |
| <b>Patients Identified Jan 2012 - Mar 2012 (2012 Q1)</b>     | 654          | 6.7          | 2,430         | 10.9         | 645          | 10.2         | 441          | 11.6         | 115        | 14.1         | 332          | 10.8         | 4,617                | 100.0 | <b>4,617</b>     | <b>10.0</b>  |
| <b>Outcome</b>                                               | 653          | 6.7          | 1,756         | 7.9          | 392          | 6.2          | 168          | 4.4          | 48         | 5.9          | 183          | 6.0          | 430                  | 9.3   | <b>3,200</b>     | <b>6.9</b>   |
| <b>Serious Liver Injury*</b>                                 |              |              |               |              |              |              |              |              |            |              |              |              |                      |       |                  |              |
| <b>ICD-9-CM Diagnosis</b>                                    |              |              |               |              |              |              |              |              |            |              |              |              |                      |       |                  |              |
| 570 Acute and Subacute Necrosis of Liver                     | 23           | 3.5          | 92            | 5.2          | 9            | 2.3          | 2            | 1.2          | 1          | 2.1          | 1            | 0.5          | 18                   | 4.2   | <b>128</b>       | <b>4.0</b>   |
| 571.5 Cirrhosis Of Liver without Mention of Alcohol          | 22           | 3.4          | 58            | 3.3          | 11           | 2.8          | 4            | 2.4          | 3          | 6.3          | 3            | 1.6          | 12                   | 2.8   | <b>101</b>       | <b>3.2</b>   |
| 572.2 Hepatic Coma                                           | 5            | 0.8          | 16            | 0.9          | 3            | 0.8          | 0            | 0.0          | 1          | 2.1          | 1            | 0.5          | 4                    | 0.9   | <b>26</b>        | <b>0.8</b>   |
| 572.4 Hepatorenal Syndrome                                   | 2            | 0.3          | 6             | 0.3          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 0            | 0.0          | 0                    | 0.0   | <b>8</b>         | <b>0.3</b>   |
| 573.0 Chronic Passive Congestion Of Liver                    | 3            | 0.5          | 22            | 1.3          | 2            | 0.5          | 1            | 0.6          | 0          | 0.0          | 2            | 1.1          | 4                    | 0.9   | <b>30</b>        | <b>0.9</b>   |
| 573.3 Hepatitis, Unspecified                                 | 25           | 3.8          | 83            | 4.7          | 12           | 3.1          | 7            | 4.2          | 2          | 4.2          | 8            | 4.4          | 21                   | 4.9   | <b>137</b>       | <b>4.3</b>   |
| 573.8 Other Specified Disrdrs of Liver                       | 146          | 22.4         | 328           | 18.7         | 111          | 28.3         | 47           | 28.0         | 7          | 14.6         | 42           | 23.0         | 93                   | 21.6  | <b>681</b>       | <b>21.3</b>  |
| 573.9 Unspecified Disorder of the Liver                      | 34           | 5.2          | 74            | 4.2          | 20           | 5.1          | 10           | 6.0          | 4          | 8.3          | 13           | 7.1          | 20                   | 4.7   | <b>155</b>       | <b>4.8</b>   |
| 782.4 Jaundice, Unspecified                                  | 28           | 4.3          | 72            | 4.1          | 17           | 4.3          | 5            | 3.0          | 1          | 2.1          | 8            | 4.4          | 18                   | 4.2   | <b>131</b>       | <b>4.1</b>   |
| 789.1 Hepatomegaly                                           | 38           | 5.8          | 90            | 5.1          | 15           | 3.8          | 12           | 7.1          | 0          | 0.0          | 11           | 6.0          | 16                   | 3.7   | <b>166</b>       | <b>5.2</b>   |
| 790.4 Nonspecific Elevation of Levels of Transaminase Or Ldh | 105          | 16.1         | 288           | 16.4         | 67           | 17.1         | 32           | 19.0         | 14         | 29.2         | 30           | 16.4         | 65                   | 15.1  | <b>536</b>       | <b>16.8</b>  |
| 790.5 Other Or Nonspecified Abnormal Serum Levels            | 139          | 21.3         | 433           | 24.7         | 101          | 25.8         | 26           | 15.5         | 7          | 14.6         | 40           | 21.9         | 113                  | 26.3  | <b>746</b>       | <b>23.3</b>  |
| 791.4 Biluria                                                | 1            | 0.2          | 2             | 0.1          | 1            | 0.3          | 0            | 0.0          | 1          | 2.1          | 1            | 0.5          | 0                    | 0.0   | <b>6</b>         | <b>0.2</b>   |
| 794.8 Nonspecific Abnormal Results of Live r Function Test   | 116          | 17.8         | 267           | 15.2         | 45           | 11.5         | 28           | 16.7         | 8          | 16.7         | 24           | 13.1         | 55                   | 12.8  | <b>488</b>       | <b>15.3</b>  |
| <b>ICD-9-CM Procedures</b>                                   |              |              |               |              |              |              |              |              |            |              |              |              |                      |       |                  |              |
| 50.11 Closed (Percutaneous) [neeedle] Biopsy of Liver        | 3            | 0.5          | 13            | 0.7          | 3            | 0.8          | 1            | 0.6          | 0          | 0.0          | 0            | 0.0          | 3                    | 0.7   | <b>20</b>        | <b>0.6</b>   |
| 50.12 Open Biopsy of Liver                                   | 0            | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 1            | 0.5          | 0                    | 0.0   | <b>1</b>         | <b>0.0</b>   |
| 50.13 Transjugular Liver Biopsy                              | 0            | 0.0          | 2             | 0.1          | 1            | 0.3          | 0            | 0.0          | 0          | 0.0          | 0            | 0.0          | 0                    | 0.0   | <b>3</b>         | <b>0.1</b>   |
| 50.14 Laparoscopic Liver Biopsy                              | 3            | 0.5          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 1            | 0.5          | 1                    | 0.2   | <b>4</b>         | <b>0.1</b>   |
| 50.91 Percutaneous Aspiration of Liver                       | 0            | 0.0          | 3             | 0.2          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 1            | 0.5          | 0                    | 0.0   | <b>4</b>         | <b>0.1</b>   |
| <b>CPT Procedures</b>                                        |              |              |               |              |              |              |              |              |            |              |              |              |                      |       |                  |              |
| 47000 Biopsy of Liver, Needle: Percutaneous                  | 3            | 0.5          | 18            | 1.0          | 2            | 0.5          | 1            | 0.6          | 0          | 0.0          | 3            | 1.6          | 7                    | 1.6   | <b>27</b>        | <b>0.8</b>   |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other         | 2            | 0.3          | 3             | 0.2          | 1            | 0.3          | 0            | 0.0          | 0          | 0.0          | 0            | 0.0          | 3                    | 0.7   | <b>6</b>         | <b>0.2</b>   |
| 47100 Biopsy of Liver, Wedge                                 | 0            | 0.0          | 1             | 0.1          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 0            | 0.0          | 0                    | 0.0   | <b>1</b>         | <b>0.0</b>   |
| 78205 Liver Imaging (Spect)                                  | 0            | 0.0          | 1             | 0.1          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 1            | 0.5          | 0                    | 0.0   | <b>2</b>         | <b>0.1</b>   |
| <b>Lab Codes</b>                                             |              |              |               |              |              |              |              |              |            |              |              |              |                      |       |                  |              |
| Elevation of alanine transaminase levels, 3x higher          | 3            | 0.5          | 4             | 0.2          | 0            | 0.0          | 0            | 0.0          | 1          | 2.1          | 0            | 0.0          | 8                    | 1.9   | <b>8</b>         | <b>0.3</b>   |
| Elevation of aspartate transaminase levels, 3x higher        | 1            | 0.2          | 1             | 0.1          | 0            | 0.0          | 0            | 0.0          | 0          | 0.0          | 0            | 0.0          | 2                    | 0.5   | <b>2</b>         | <b>0.1</b>   |
| Elevation of bilirubin level, 1.5x higher                    | 0            | 0.0          | 4             | 0.2          | 0            | 0.0          | 0            | 0.0          | 1          | 2.1          | 0            | 0.0          | 5                    | 1.2   | <b>5</b>         | <b>0.2</b>   |

\*Liver injury diagnoses reported on date of first liver injury diagnosis after index date, for patients exiting liver injury monitoring cohort in this period due to liver injury diagnosis.

**Table 3. Interstitial Lung Disease Surveillance, US DoD Database: January to March 2012**

| US DoD Database Surveillance                                       | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Identified in 2012Q1 |       | Cumulative Total |       |
|--------------------------------------------------------------------|-------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|----------------------|-------|------------------|-------|
|                                                                    | N           | %     | N          | %     | N       | %     | N          | %     | N          | %     | N           | %     | N                    | %     | N                | %     |
| Total patients identified through 2012 Q1                          | 9,813       | 100.0 | 22,363     | 100.0 | 6,294   | 100.0 | 3,811      | 100.0 | 817        | 100.0 | 3,070       | 100.0 |                      |       | 46,168           | 100.0 |
| Patients identified prior to 2012 Q1                               | 9,159       | 100.0 | 19,933     | 100.0 | 5,649   | 100.0 | 3,370      | 100.0 | 702        | 100.0 | 2,738       | 100.0 |                      |       | 41,551           | 100.0 |
| Patients Identified Jan 2012 - Mar 2012 (2012 Q1)                  | 654         | 6.7   | 2,430      | 10.9  | 645     | 10.2  | 441        | 11.6  | 115        | 14.1  | 332         | 10.8  | 4,617                | 100.0 | 4,617            | 10.0  |
| Outcome                                                            | 307         | 3.1   | 964        | 4.3   | 187     | 3.0   | 75         | 2.0   | 28         | 3.4   | 89          | 2.9   | 193                  |       | 1,650            | 3.6   |
| <b>Interstitial Lung Disease*</b>                                  |             |       |            |       |         |       |            |       |            |       |             |       |                      |       |                  |       |
| 495.9 Unspecified Allergic Alveolitis and Pneumonitis              | 2           | 0.0   | 13         | 0.1   | 1       | 0.0   | 0          | 0.0   | 0          | 0.0   | 1           | 0.0   | 5                    | 0.1   | 17               | 0.0   |
| 515 Postinflammatory Pulmonary Fibrosis                            | 256         | 2.6   | 812        | 3.6   | 164     | 2.6   | 65         | 1.7   | 27         | 3.3   | 78          | 2.5   | 177                  | 3.8   | 1,402            | 3.0   |
| 516.3 Idiopathic Fibrosing Alveolitis                              | 18          | 0.2   | 43         | 0.2   | 7       | 0.1   | 2          | 0.1   | 0          | 0.0   | 3           | 0.1   | 0                    | 0.0   | 73               | 0.2   |
| 516.8 Other Specified Alveolar and Parietoalveolar Pneumonopathies | 13          | 0.1   | 43         | 0.2   | 8       | 0.1   | 5          | 0.1   | 1          | 0.1   | 2           | 0.1   | 13                   | 0.3   | 72               | 0.2   |
| 516.9 Unspecified Alveolar and Parietoalveolar Pneumonopathy       | 18          | 0.2   | 64         | 0.3   | 8       | 0.1   | 4          | 0.1   | 0          | 0.0   | 5           | 0.2   | 1                    | 0.0   | 99               | 0.2   |

\* Interstitial lung disease diagnoses reported on date of first ILD diagnosis after index date, for patients exiting ILD monitoring cohort in this period due to ILD diagnosis.

**Distribution by Age and Gender for Each Drug Cohort all Patients from Retrospective to 2012 Q1 Surveillance, US DoD Database**

| Overall Age Groups | Dronedarone (n=10,298) |            | Amiodarone (n=24,321) |            | Sotalol (n=6,786) |            | Flecainide (n=4,152) |            | Dofetilide (n=886) |            | Propafenone (n=3,296) |            | Total (N=49,739) |            |
|--------------------|------------------------|------------|-----------------------|------------|-------------------|------------|----------------------|------------|--------------------|------------|-----------------------|------------|------------------|------------|
|                    | N                      | %          | N                     | %          | N                 | %          | N                    | %          | N                  | %          | N                     | %          | N                | %          |
| < 18               | 0                      | 0.0        | 5                     | 0.0        | 4                 | 0.1        | 3                    | 0.1        | 0                  | 0.0        | 1                     | 0.0        | 13               | 0.0        |
| 18-24              | 5                      | 0.0        | 8                     | 0.0        | 6                 | 0.1        | 36                   | 0.9        | 1                  | 0.1        | 6                     | 0.2        | 62               | 0.1        |
| 25-34              | 31                     | 0.3        | 26                    | 0.1        | 26                | 0.4        | 100                  | 2.4        | 5                  | 0.6        | 33                    | 1.0        | 221              | 0.4        |
| 35-44              | 107                    | 1.0        | 80                    | 0.3        | 50                | 0.7        | 190                  | 4.6        | 6                  | 0.7        | 75                    | 2.3        | 508              | 1.0        |
| 45-54              | 413                    | 4.0        | 496                   | 2.0        | 246               | 3.6        | 363                  | 8.7        | 44                 | 5.0        | 223                   | 6.8        | 1,785            | 3.6        |
| 55-64              | 1,555                  | 15.1       | 2,609                 | 10.7       | 1,001             | 14.8       | 833                  | 20.1       | 172                | 19.4       | 598                   | 18.1       | 6,768            | 13.6       |
| 65-74              | 3,726                  | 36.2       | 7,656                 | 31.5       | 2,423             | 35.7       | 1,449                | 34.9       | 356                | 40.1       | 1,165                 | 35.3       | 16,775           | 33.7       |
| 75-84              | 3,542                  | 34.4       | 9,815                 | 40.4       | 2,384             | 35.1       | 965                  | 23.2       | 262                | 29.5       | 940                   | 28.5       | 17,908           | 36.0       |
| 85+                | 919                    | 8.9        | 3,626                 | 14.9       | 646               | 9.5        | 213                  | 5.1        | 40                 | 4.5        | 255                   | 7.7        | 5,699            | 11.5       |
| <b>Total</b>       | <b>10,298</b>          | <b>100</b> | <b>24,321</b>         | <b>100</b> | <b>6,786</b>      | <b>100</b> | <b>4,152</b>         | <b>100</b> | <b>886</b>         | <b>100</b> | <b>3,296</b>          | <b>100</b> | <b>49,739</b>    | <b>100</b> |

| Female Age Groups     | Dronedarone  |             | Amiodarone   |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             | Total         |             |
|-----------------------|--------------|-------------|--------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
|                       | N            | %           | N            | %           | N            | %           | N            | %           | N          | %           | N            | %           | N             | %           |
| Females, < 18         | 0            | 0.0         | 3            | 0.0         | 2            | 0.0         | 1            | 0.0         | 0          | 0.0         | 1            | 0.0         | 7             | 0.0         |
| Females, 18-24        | 1            | 0.0         | 0            | 0.0         | 4            | 0.1         | 7            | 0.2         | 1          | 0.1         | 2            | 0.1         | 15            | 0.0         |
| Females, 25-34        | 6            | 0.1         | 6            | 0.0         | 14           | 0.2         | 35           | 0.8         | 2          | 0.2         | 8            | 0.2         | 71            | 0.1         |
| Females, 35-44        | 23           | 0.2         | 16           | 0.1         | 19           | 0.3         | 48           | 1.2         | 1          | 0.1         | 13           | 0.4         | 120           | 0.2         |
| Females, 45-54        | 119          | 1.2         | 120          | 0.5         | 66           | 1.0         | 113          | 2.7         | 10         | 1.1         | 72           | 2.2         | 500           | 1.0         |
| Females, 55-64        | 578          | 5.6         | 708          | 2.9         | 307          | 4.5         | 356          | 8.6         | 44         | 5.0         | 234          | 7.1         | 2,227         | 4.5         |
| Females, 65-74        | 1,607        | 15.6        | 2,633        | 10.8        | 1,034        | 15.2        | 763          | 18.4        | 113        | 12.7        | 604          | 18.3        | 6,754         | 13.6        |
| Females, 75-84        | 1,758        | 17.1        | 4,055        | 16.7        | 1,209        | 17.8        | 607          | 14.6        | 107        | 12.1        | 547          | 16.6        | 8,283         | 16.7        |
| Females, 85+          | 544          | 5.3         | 1,903        | 7.8         | 399          | 5.9         | 154          | 3.7         | 20         | 2.3         | 175          | 5.3         | 3,195         | 6.4         |
| <b>Females, Total</b> | <b>4,636</b> | <b>45.0</b> | <b>9,444</b> | <b>38.8</b> | <b>3,054</b> | <b>45.0</b> | <b>2,084</b> | <b>50.2</b> | <b>298</b> | <b>33.6</b> | <b>1,656</b> | <b>50.2</b> | <b>21,172</b> | <b>42.6</b> |

| Male Age Groups     | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             | Total         |             |
|---------------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
|                     | N            | %           | N             | %           | N            | %           | N            | %           | N          | %           | N            | %           | N             | %           |
| Males, < 18         | 0            | 0.0         | 2             | 0.0         | 2            | 0.0         | 2            | 0.0         | 0          | 0.0         | 0            | 0.0         | 6             | 0.0         |
| Males, 18-24        | 4            | 0.0         | 8             | 0.0         | 2            | 0.0         | 29           | 0.7         | 0          | 0.0         | 4            | 0.1         | 47            | 0.1         |
| Males, 25-34        | 25           | 0.2         | 20            | 0.1         | 12           | 0.2         | 65           | 1.6         | 3          | 0.3         | 25           | 0.8         | 150           | 0.3         |
| Males, 35-44        | 84           | 0.8         | 64            | 0.3         | 31           | 0.5         | 142          | 3.4         | 5          | 0.6         | 62           | 1.9         | 388           | 0.8         |
| Males, 45-54        | 294          | 2.9         | 376           | 1.5         | 180          | 2.7         | 250          | 6.0         | 34         | 3.8         | 151          | 4.6         | 1,285         | 2.6         |
| Males, 55-64        | 977          | 9.5         | 1,901         | 7.8         | 694          | 10.2        | 477          | 11.5        | 128        | 14.4        | 364          | 11.0        | 4,541         | 9.1         |
| Males, 65-74        | 2,119        | 20.6        | 5,023         | 20.7        | 1,389        | 20.5        | 686          | 16.5        | 243        | 27.4        | 561          | 17.0        | 10,021        | 20.1        |
| Males, 75-84        | 1,784        | 17.3        | 5,760         | 23.7        | 1,175        | 17.3        | 358          | 8.6         | 155        | 17.5        | 393          | 11.9        | 9,625         | 19.4        |
| Males, 85+          | 375          | 3.6         | 1,723         | 7.1         | 247          | 3.6         | 59           | 1.4         | 20         | 2.3         | 80           | 2.4         | 2,504         | 5.0         |
| <b>Males, Total</b> | <b>5,662</b> | <b>55.0</b> | <b>14,877</b> | <b>61.2</b> | <b>3,732</b> | <b>55.0</b> | <b>2,068</b> | <b>49.8</b> | <b>588</b> | <b>66.3</b> | <b>1,640</b> | <b>49.8</b> | <b>28,567</b> | <b>57.4</b> |

## Age Group Demographic for Study Cohorts , July 2009 - 2012Q1, US DoD Database

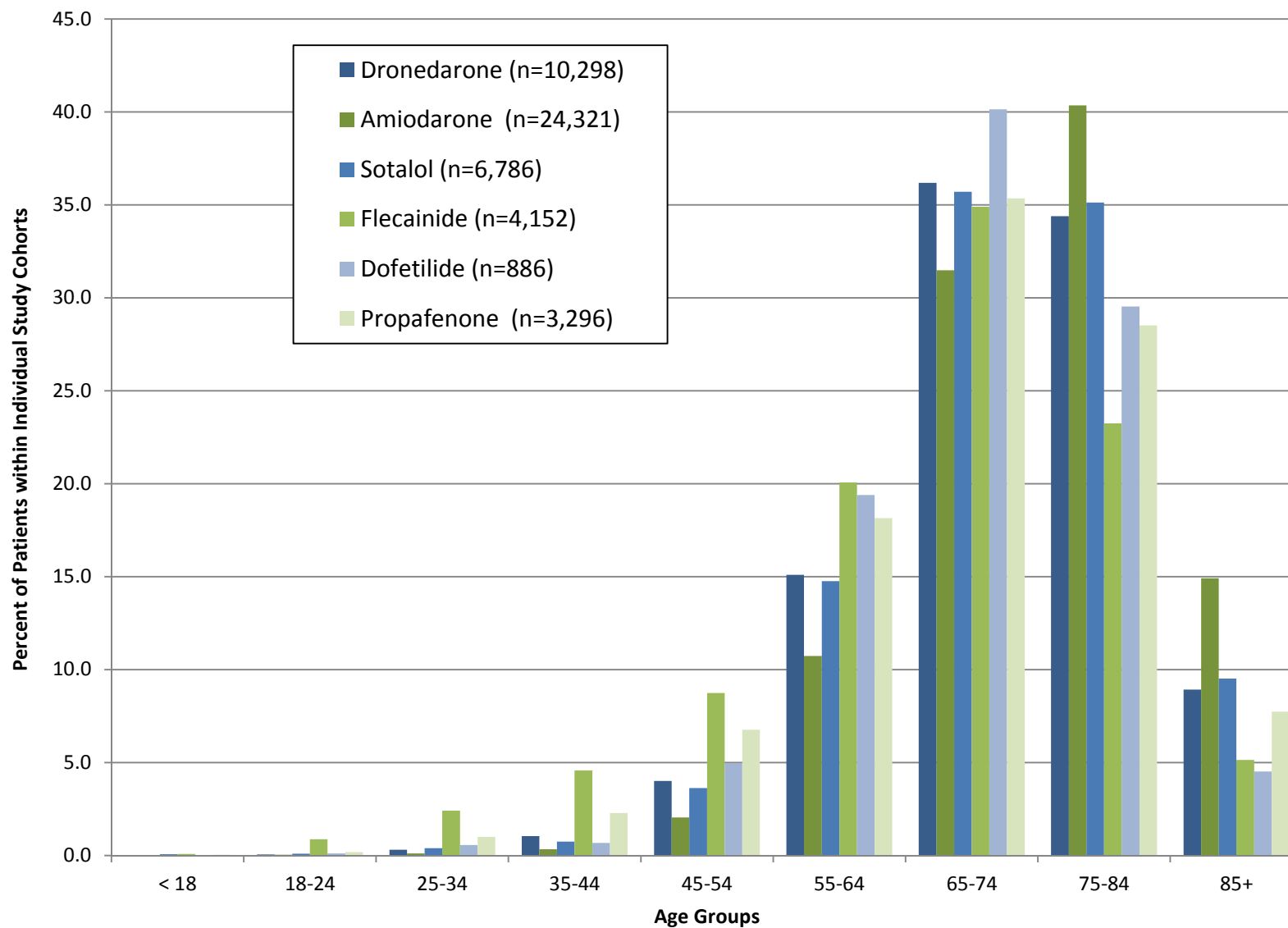






**Table 1. Number of Patients by Drug Cohort and Screening Criteria, US DoD Database: April to June 2012**

| Description                                                      | Dronedarone  | Amiodarone    | Sotalol      | Flecainide   | Dofetilide   | Propafenone  | Total           |
|------------------------------------------------------------------|--------------|---------------|--------------|--------------|--------------|--------------|-----------------|
| Patients with a study drug between 4/1/2012 and 6/30/2012        | 7,151        | 20,265        | 12,749       | 7,140        | 2,073        | 5,221        | 53,765 *        |
| Less patients already in previous surveillance dataset           | 4,485        | 7,204         | 3,825        | 2,231        | 872          | 1,485        | 19,753 *        |
| <b>Remaining patients</b>                                        | <b>2,666</b> | <b>13,061</b> | <b>8,924</b> | <b>4,909</b> | <b>1,201</b> | <b>3,736</b> | <b>34,012 *</b> |
| Assign the first study drug as the cohort                        | 2,591        | 12,889        | 8,823        | 4,853        | 1,173        | 3,683        | 34,012          |
| Less patients without 365 days of eligibility prior to indexdate | 2,012        | 10,112        | 8,157        | 4,367        | 1,092        | 3,376        | 29,116          |
| Remaining patients                                               | 579          | 2,777         | 666          | 486          | 81           | 307          | 4,896           |
| Less patients without AF in the year prior to indexdate          | 93           | 816           | 168          | 144          | 9            | 81           | 1,311           |
| Remaining patients                                               | 486          | 1,961         | 498          | 342          | 72           | 226          | 3,585           |
| Less patients with the index drug in the year prior to indexdate | 1            | 2             | 6            | 0            | 2            | 0            | 11              |
| Remaining patients                                               | 485          | 1,959         | 492          | 342          | 70           | 226          | 3,574           |
| Less patients with multiple study drugs on index date            | 0            | 1             | 0            | 0            | 0            | 0            | 1               |
| Remaining patients                                               | 485          | 1,958         | 492          | 342          | 70           | 226          | 3,573           |
| Less patients with date of death preceding index date            | 0            | 0             | 0            | 1            | 0            | 0            | 1               |
| <b>Patients in cohort</b>                                        | <b>485</b>   | <b>1,958</b>  | <b>492</b>   | <b>341</b>   | <b>70</b>    | <b>226</b>   | <b>3,572</b>    |

\*Number of unique patients

**Table 2. Demographics by Age and Gender for Each Drug Cohort, US DoD Database, July 1, 2009 to June 2012**

| Description                                                     | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide |              | Propafenone  |              | Total         |              |
|-----------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|------------|--------------|--------------|--------------|---------------|--------------|
|                                                                 | N             | %            | N             | %            | N            | %            | N            | %            | N          | %            | N            | %            | N             | %            |
| <b>Total Patients in the Surveillance Dataset as of 2012 Q2</b> | <b>10,298</b> | <b>100.0</b> | <b>24,321</b> | <b>100.0</b> | <b>6,786</b> | <b>100.0</b> | <b>4,152</b> | <b>100.0</b> | <b>887</b> | <b>100.0</b> | <b>3,296</b> | <b>100.0</b> | <b>49,740</b> | <b>100.0</b> |
| < 18                                                            | 0             | 0.0          | 5             | 0.0          | 4            | 0.1          | 3            | 0.1          | 0          | 0.0          | 1            | 0.0          | 13            | 0.0          |
| Female                                                          | 0             | 0.0          | 3             | 0.0          | 2            | 0.0          | 1            | 0.0          | 0          | 0.0          | 1            | 0.0          | 7             | 0.0          |
| Male                                                            | 0             | 0.0          | 2             | 0.0          | 2            | 0.0          | 2            | 0.0          | 0          | 0.0          | 0            | 0.0          | 6             | 0.0          |
| 18-24                                                           | 5             | 0.0          | 8             | 0.0          | 6            | 0.1          | 36           | 0.9          | 1          | 0.1          | 6            | 0.2          | 62            | 0.1          |
| Female                                                          | 1             | 0.0          | 0             | 0.0          | 4            | 0.1          | 7            | 0.2          | 1          | 0.1          | 2            | 0.1          | 15            | 0.0          |
| Male                                                            | 4             | 0.0          | 8             | 0.0          | 2            | 0.0          | 29           | 0.7          | 0          | 0.0          | 4            | 0.1          | 47            | 0.1          |
| 25-34                                                           | 31            | 0.3          | 26            | 0.1          | 26           | 0.4          | 100          | 2.4          | 5          | 0.6          | 33           | 1.0          | 221           | 0.4          |
| Female                                                          | 6             | 0.1          | 6             | 0.0          | 14           | 0.2          | 35           | 0.8          | 2          | 0.2          | 8            | 0.2          | 71            | 0.1          |
| Male                                                            | 25            | 0.2          | 20            | 0.1          | 12           | 0.2          | 65           | 1.6          | 3          | 0.3          | 25           | 0.8          | 150           | 0.3          |
| 35-44                                                           | 107           | 1.0          | 80            | 0.3          | 50           | 0.7          | 190          | 4.6          | 6          | 0.7          | 75           | 2.3          | 508           | 1.0          |
| Female                                                          | 23            | 0.2          | 16            | 0.1          | 19           | 0.3          | 48           | 1.2          | 1          | 0.1          | 13           | 0.4          | 120           | 0.2          |
| Male                                                            | 84            | 0.8          | 64            | 0.3          | 31           | 0.5          | 142          | 3.4          | 5          | 0.6          | 62           | 1.9          | 388           | 0.8          |
| 45-54                                                           | 413           | 4.0          | 496           | 2.0          | 246          | 3.6          | 363          | 8.7          | 44         | 5.0          | 223          | 6.8          | 1,785         | 3.6          |
| Female                                                          | 119           | 1.2          | 120           | 0.5          | 66           | 1.0          | 113          | 2.7          | 10         | 1.1          | 72           | 2.2          | 500           | 1.0          |
| Male                                                            | 294           | 2.9          | 376           | 1.5          | 180          | 2.7          | 250          | 6.0          | 34         | 3.8          | 151          | 4.6          | 1,285         | 2.6          |
| 55-64                                                           | 1,555         | 15.1         | 2,609         | 10.7         | 1,001        | 14.8         | 833          | 20.1         | 172        | 19.4         | 598          | 18.1         | 6,768         | 13.6         |
| Female                                                          | 578           | 5.6          | 708           | 2.9          | 307          | 4.5          | 356          | 8.6          | 44         | 5.0          | 234          | 7.1          | 2,227         | 4.5          |
| Male                                                            | 977           | 9.5          | 1,901         | 7.8          | 694          | 10.2         | 477          | 11.5         | 128        | 14.4         | 364          | 11.0         | 4,541         | 9.1          |
| 65-74                                                           | 3,726         | 36.2         | 7,656         | 31.5         | 2,423        | 35.7         | 1,449        | 34.9         | 356        | 40.1         | 1,165        | 35.3         | 16,775        | 33.7         |
| Female                                                          | 1,607         | 15.6         | 2,633         | 10.8         | 1,034        | 15.2         | 763          | 18.4         | 113        | 12.7         | 604          | 18.3         | 6,754         | 13.6         |
| Male                                                            | 2,119         | 20.6         | 5,023         | 20.7         | 1,389        | 20.5         | 686          | 16.5         | 243        | 27.4         | 561          | 17.0         | 10,021        | 20.1         |
| Unknown                                                         | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 1          | 0.1          | 0            | 0.0          | 1             | 0.0          |
| 75-84                                                           | 3,542         | 34.4         | 9,815         | 40.4         | 2,384        | 35.1         | 965          | 23.2         | 262        | 29.5         | 940          | 28.5         | 17,908        | 36.0         |
| Female                                                          | 1,758         | 17.1         | 4,055         | 16.7         | 1,209        | 17.8         | 607          | 14.6         | 107        | 12.1         | 547          | 16.6         | 8,283         | 16.7         |
| Male                                                            | 1,784         | 17.3         | 5,760         | 23.7         | 1,175        | 17.3         | 358          | 8.6          | 155        | 17.5         | 393          | 11.9         | 9,625         | 19.4         |
| 85+                                                             | 919           | 8.9          | 3,626         | 14.9         | 646          | 9.5          | 213          | 5.1          | 40         | 4.5          | 255          | 7.7          | 5,699         | 11.5         |
| Female                                                          | 544           | 5.3          | 1,903         | 7.8          | 399          | 5.9          | 154          | 3.7          | 20         | 2.3          | 175          | 5.3          | 3,195         | 6.4          |
| Male                                                            | 375           | 3.6          | 1,723         | 7.1          | 247          | 3.6          | 59           | 1.4          | 20         | 2.3          | 80           | 2.4          | 2,504         | 5.0          |
| <b>Total</b>                                                    |               |              |               |              |              |              |              |              |            |              |              |              |               |              |
| <b>Female</b>                                                   | <b>4,636</b>  | <b>45.0</b>  | <b>9,444</b>  | <b>38.8</b>  | <b>3,054</b> | <b>45.0</b>  | <b>2,084</b> | <b>50.2</b>  | <b>298</b> | <b>33.6</b>  | <b>1,656</b> | <b>50.2</b>  | <b>21,172</b> | <b>42.6</b>  |
| <b>Male</b>                                                     | <b>5,662</b>  | <b>55.0</b>  | <b>14,877</b> | <b>61.2</b>  | <b>3,732</b> | <b>55.0</b>  | <b>2,068</b> | <b>49.8</b>  | <b>588</b> | <b>66.3</b>  | <b>1,640</b> | <b>49.8</b>  | <b>28,567</b> | <b>57.4</b>  |

**Table 3. Overall Serious Liver Injury Surveillance Updated with 2012Q2 Data, US DoD Database: July 1, 2009 - June 30, 2012**

| US DoD Database Surveillance                                 | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Identified in 2012 Q2 |       | Cumulative Total |       |
|--------------------------------------------------------------|-------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|-----------------------|-------|------------------|-------|
|                                                              | N           | %     | N          | %     | N       | %     | N          | %     | N          | %     | N           | %     | N                     | %     | N                | %     |
| Total patients identified through 2012 Q2                    | 10,298      | 100.0 | 24,321     | 100.0 | 6,786   | 100.0 | 4,152      | 100.0 | 887        | 100.0 | 3,296       | 100.0 |                       |       | 49,740           | 100.0 |
| Patients identified prior to 2012 Q2                         | 9,813       | 95.3  | 22,363     | 91.9  | 6,294   | 92.7  | 3,811      | 91.8  | 817        | 92.1  | 3,070       | 93.1  |                       |       | 46,168           | 92.8  |
| Patients identified Apr 2012 - Jun 2012 (2012 Q2)            | 485         | 4.7   | 1,958      | 8.1   | 492     | 7.3   | 341        | 8.2   | 70         | 7.9   | 226         | 6.9   | 3,572                 | 100.0 | 3,572            | 7.2   |
| Patients with Serious Liver Injury Outcomes*                 | 740         | 7.2   | 1,981      | 8.1   | 439     | 6.5   | 195        | 4.7   | 53         | 6.0   | 195         | 5.9   | 403                   | 11.2  | 3,603            | 7.2   |
| <b>ICD-9-CM Diagnosis</b>                                    |             |       |            |       |         |       |            |       |            |       |             |       |                       |       |                  |       |
| 570 Acute and subacute necrosis of liver                     | 23          | 0.2   | 101        | 0.4   | 10      | 0.1   | 3          | 0.1   | 2          | 0.2   | 1           | 0.0   | 12                    | 0.3   | 140              | 0.3   |
| 571.5 Cirrhosis of liver without mention of alcohol          | 29          | 0.3   | 63         | 0.3   | 13      | 0.2   | 4          | 0.1   | 4          | 0.5   | 4           | 0.1   | 16                    | 0.4   | 117              | 0.2   |
| 572.2 Hepatic coma                                           | 6           | 0.1   | 20         | 0.1   | 4       | 0.1   | 0          | 0.0   | 1          | 0.1   | 1           | 0.0   | 6                     | 0.2   | 32               | 0.1   |
| 572.4 Hepatorenal syndrome                                   | 2           | 0.0   | 6          | 0.0   | 0       | 0.0   | 0          | 0.0   | 1          | 0.1   | 0           | 0.0   | 1                     | 0.0   | 9                | 0.0   |
| 573.0 Chronic passive congestion of liver                    | 3           | 0.0   | 23         | 0.1   | 2       | 0.0   | 1          | 0.0   | 0          | 0.0   | 2           | 0.1   | 1                     | 0.0   | 31               | 0.1   |
| 573.3 Hepatitis, unspecified                                 | 28          | 0.3   | 94         | 0.4   | 14      | 0.2   | 7          | 0.2   | 2          | 0.2   | 8           | 0.2   | 16                    | 0.4   | 153              | 0.3   |
| 573.8 Other specified disorders of liver                     | 167         | 1.6   | 364        | 1.5   | 122     | 1.8   | 54         | 1.3   | 8          | 0.9   | 48          | 1.5   | 82                    | 2.3   | 763              | 1.5   |
| 573.9 Unspecified disorder of liver                          | 39          | 0.4   | 89         | 0.4   | 22      | 0.3   | 10         | 0.2   | 4          | 0.5   | 15          | 0.5   | 24                    | 0.7   | 179              | 0.4   |
| 782.4 Jaundice, unspecified                                  | 35          | 0.3   | 81         | 0.3   | 18      | 0.3   | 7          | 0.2   | 2          | 0.2   | 11          | 0.3   | 23                    | 0.6   | 154              | 0.3   |
| 789.1 Hepatomegaly                                           | 39          | 0.4   | 98         | 0.4   | 17      | 0.3   | 13         | 0.3   | 0          | 0.0   | 11          | 0.3   | 12                    | 0.3   | 178              | 0.4   |
| 790.4 Nonspecific elevation of levels of transaminase or LDH | 118         | 1.1   | 329        | 1.4   | 75      | 1.1   | 37         | 0.9   | 15         | 1.7   | 32          | 1.0   | 70                    | 2.0   | 606              | 1.2   |
| 790.5 Other or nonspecified abnormal serum levels            | 161         | 1.6   | 488        | 2.0   | 114     | 1.7   | 31         | 0.7   | 7          | 0.8   | 41          | 1.2   | 96                    | 2.7   | 842              | 1.7   |
| 791.4 Biliuria                                               | 1           | 0.0   | 2          | 0.0   | 1       | 0.0   | 0          | 0.0   | 1          | 0.1   | 1           | 0.0   | 0                     | 0.0   | 6                | 0.0   |
| 794.8 Nonspecific abnormal results of liver function test    | 120         | 1.2   | 300        | 1.2   | 50      | 0.7   | 32         | 0.8   | 8          | 0.9   | 26          | 0.8   | 48                    | 1.3   | 536              | 1.1   |
| <b>ICD-9-CM Procedures</b>                                   |             |       |            |       |         |       |            |       |            |       |             |       |                       |       |                  |       |
| 50.11 Closed (percutaneous) [needle] biopsy of liver         | 3           | 0.0   | 14         | 0.1   | 3       | 0.0   | 1          | 0.0   | 0          | -     | 0           | -     | 1                     | 0.0   | 21               | 0.0   |
| 50.12 Open biopsy of liver                                   | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 1           | 0.0   | 0                     | 0.0   | 1                | 0.0   |
| 50.13 Transjugular liver biopsy                              | 0           | -     | 2          | 0.0   | 1       | 0.0   | 0          | -     | 0          | -     | 0           | -     | 0                     | 0.0   | 3                | 0.0   |
| 50.14 Laparoscopic liver biopsy                              | 3           | 0.0   | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 1           | 0.0   | 0                     | 0.0   | 4                | 0.0   |
| 50.5 Liver transplant                                        | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | 0.0   | 0                | -     |
| 50.51 Auxiliary liver transplant                             | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | 0.0   | 0                | -     |
| 50.59 Other transplant of liver                              | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | 0.0   | 0                | -     |
| 50.91 Percutaneous aspiration of liver                       | 0           | -     | 4          | 0.0   | 0       | -     | 0          | -     | 0          | -     | 1           | 0.0   | 1                     | 0.0   | 5                | 0.0   |
| <b>CPT Procedures</b>                                        |             |       |            |       |         |       |            |       |            |       |             |       |                       |       |                  |       |
| 47000 Biopsy of Liver, Needle: Percutaneous                  | 5           | 0.0   | 19         | 0.1   | 4       | 0.1   | 2          | 0.0   | 0          | -     | 3           | 0.1   | 6                     | 0.2   | 33               | 0.1   |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other         | 3           | 0.0   | 4          | 0.0   | 1       | 0.0   | 0          | -     | 0          | -     | 0           | -     | 2                     | 0.1   | 8                | 0.0   |
| 47100 Biopsy of Liver, Wedge                                 | 1           | 0.0   | 1          | 0.0   | 0       | -     | 1          | 0.0   | 0          | -     | 0           | -     | 2                     | 0.1   | 3                | 0.0   |
| 47135 Liver allotransplant; orthotopic, partial or whole     | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | -     | 0                | -     |
| 47136 Liver allotransplant; heterotopic, partial or whole    | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | -     | 0                | -     |
| 78205 Liver Imaging (Spect)                                  | 0           | -     | 1          | 0.0   | 0       | -     | 0          | -     | 0          | -     | 1           | 0.0   | 0                     | -     | 2                | 0.0   |
| 78206 Liver imaging (SPECT); with vascular flow              | 0           | -     | 0          | -     | 0       | -     | 0          | -     | 0          | -     | 0           | -     | 0                     | -     | 0                | -     |
| <b>Lab Codes</b>                                             |             |       |            |       |         |       |            |       |            |       |             |       |                       |       |                  |       |
| 1742-6 Elevation of alanine transaminase levels, 3x higher   | 6           | 0.1   | 9          | 0.0   | 1       | 0.0   | 2          | 0.0   | 2          | 0.2   | 0           | -     | 0                     | -     | 20               | 0.0   |
| 1920-8 Elevation of aspartate transaminase levels, 3x higher | 5           | 0.0   | 6          | 0.0   | 0       | -     | 1          | 0.0   | 1          | 0.1   | 0           | -     | 0                     | -     | 13               | 0.0   |
| 1975-2 Elevation of bilirubin level, 1.5x higher             | 2           | 0.0   | 6          | 0.0   | 0       | -     | 0          | -     | 2          | 0.2   | 0           | -     | 0                     | -     | 10               | 0.0   |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the Overall Surveillance Study Medication Cohort patient count.

**Table 4. Overall Interstitial Lung Disease Counts Updated with 2012Q2 Data, US DoD Database: July 1, 2009 - June 30, 2012**

| US DoD Database Surveillance                                       | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide |              | Propafenone  |              | Identified in 2012 Q2 |             | Total         |              |
|--------------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|------------|--------------|--------------|--------------|-----------------------|-------------|---------------|--------------|
|                                                                    | N             | %            | N             | %            | N            | %            | N            | %            | N          | %            | N            | %            | N                     | %           | N             | %            |
| <b>Total patients identified through 2012 Q2</b>                   | <b>10,298</b> | <b>100.0</b> | <b>24,321</b> | <b>100.0</b> | <b>6,786</b> | <b>100.0</b> | <b>4,152</b> | <b>100.0</b> | <b>887</b> | <b>100.0</b> | <b>3,296</b> | <b>100.0</b> |                       |             | <b>49,740</b> | <b>100.0</b> |
| Patients identified prior to 2012 Q2                               | 9,813         | 95.3         | 22,363        | 91.9         | 6,294        | 92.7         | 3,811        | 91.8         | 817        | 92.1         | 3,070        | 93.1         |                       |             | 46,168        | 92.8         |
| Patients identified Apr 2012 - Jun 2012 (2012 Q2)                  | 485           | 4.7          | 1,958         | 8.1          | 492          | 7.3          | 341          | 8.2          | 70         | 7.9          | 226          | 6.9          | 3,572                 | 100.0       | 3,572         | 7.2          |
| <b>Patients with Interstitial Lung Disease Outcomes*</b>           | <b>345</b>    | <b>3.4</b>   | <b>1,069</b>  | <b>4.4</b>   | <b>210</b>   | <b>3.1</b>   | <b>85</b>    | <b>2.0</b>   | <b>33</b>  | <b>3.7</b>   | <b>96</b>    | <b>2.9</b>   | <b>381</b>            | <b>10.7</b> | <b>1,838</b>  | <b>3.7</b>   |
| 495.9 Unspecified allergic alveolitis and pneumonitis              | 2             | 0.0          | 14            | 0.1          | 2            | 0.0          |              | 0.0          |            | 0.0          | 2            | 0.1          | 8                     | 0.2         | 20            | 0.0          |
| 515 Postinflammatory pulmonary fibrosis                            | 292           | 2.8          | 909           | 3.7          | 185          | 2.7          | 74           | 1.8          | 31         | 3.5          | 84           | 2.5          | 350                   | 9.8         | 1,575         | 3.2          |
| 516.3 Idiopathic fibrosing alveolitis                              | 18            | 0.2          | 43            | 0.2          | 7            | 0.1          | 2            | 0.0          |            | 0.0          | 3            | 0.1          | 0                     | 0.0         | 73            | 0.1          |
| 516.8 Other specified alveolar and parietoalveolar pneumonopathies | 14            | 0.1          | 48            | 0.2          | 9            | 0.1          | 6            | 0.1          | 2          | 0.2          | 2            | 0.1          | 22                    | 0.6         | 81            | 0.2          |
| 516.9 Unspecified alveolar and parietoalveolar pneumonopathy       | 19            | 0.2          | 66            | 0.3          | 8            | 0.1          | 4            | 0.1          |            | 0.0          | 5            | 0.2          | 4                     | 0.1         | 102           | 0.2          |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the Overall Surveillance Study Medication Cohort patient count.

**Table 1. Number of Patients by Drug Cohort and Screening Criteria, US DoD Database: July to September 2012**

| Description                                                      | Dronedarone | Amiodarone   | Sotalol    | Flecainide | Dofetilide | Propafenone | Total*        |
|------------------------------------------------------------------|-------------|--------------|------------|------------|------------|-------------|---------------|
| Patients with a study drug between 7/1/2012 and 9/30/2012        | 7,050       | 20,161       | 12,748     | 7,309      | 2,161      | 5,200       | <b>53,805</b> |
| Less patients already in previous surveillance dataset           | 3,838       | 5,699        | 3,329      | 1,938      | 806        | 1,284       | <b>16,666</b> |
| Remaining patients                                               | 3,212       | 14,462       | 9,419      | 5,371      | 1,355      | 3,916       | <b>37,139</b> |
|                                                                  |             |              |            |            |            |             |               |
| Assign the first study drug as the cohort                        | 3,116       | 14,239       | 9,315      | 5,290      | 1,328      | 3,851       | <b>37,139</b> |
| Less patients without 365 days of eligibility prior to indexdate | 735         | 2,549        | 1,112      | 781        | 184        | 412         | <b>5,773</b>  |
| Remaining patients                                               | 2,381       | 11,690       | 8,203      | 4,509      | 1,144      | 3,439       | <b>31,366</b> |
| Less patients without AF in the year prior to indexdate          | 776         | 4,271        | 2,651      | 1,688      | 166        | 1,064       | <b>10,616</b> |
| Remaining patients                                               | 1,605       | 7,419        | 5,552      | 2,821      | 978        | 2,375       | <b>20,750</b> |
| Less patients with the index drug in the year prior to indexdate | 1,279       | 5,913        | 5,142      | 2,586      | 876        | 2,226       | <b>18,022</b> |
| Remaining patients                                               | 326         | 1,506        | 410        | 235        | 102        | 149         | <b>2,728</b>  |
| Less patients with multiple study drugs on index date            | 0           | 1            | 0          | 0          | 0          | 0           | <b>1</b>      |
| Remaining patients                                               | 326         | 1,505        | 410        | 235        | 102        | 149         | <b>2,727</b>  |
| Less patients with date of death preceding index date            | 0           | 0            | 0          | 0          | 0          | 0           | <b>0</b>      |
| <b>Patients in cohort</b>                                        | <b>326</b>  | <b>1,505</b> | <b>410</b> | <b>235</b> | <b>102</b> | <b>149</b>  | <b>2,727</b>  |

\*Number of unique patients

**Table 2. Number of Patients Diagnosed with Serious Liver Injury, by Cohort and Period, US DoD Database: July 1, 2009 - Sep 30, 2012**

| US DoD Database Surveillance                                 | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup> (Jul 2009 - Sep 2012) |       |            |       |         |       |            |       |            |       |             |       | Identified in<br>Current Quarter<br>Only (Jul-Sep<br>2012) |       | Cumulative SLI<br>Total<br>(Jul 2009 - Sep<br>2012) |       |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|------------------------------------------------------------|-------|-----------------------------------------------------|-------|
|                                                              | Dronedarone                                                                                                                        |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       |                                                            |       |                                                     |       |
|                                                              | N                                                                                                                                  | %     | N          | %     | N       | %     | N          | %     | N          | %     | N           | %     | N                                                          | %     | N                                                   | %     |
| Total patients identified through 2012 Q3                    | 10,624                                                                                                                             | 100.0 | 25,826     | 100.0 | 7,196   | 100.0 | 4,387      | 100.0 | 989        | 100.0 | 3,445       | 100.0 |                                                            |       | 52,467                                              | 100.0 |
| Patients identified prior to 2012 Q3                         | 10,298                                                                                                                             | 96.9  | 24,321     | 94.2  | 6,786   | 94.3  | 4,152      | 94.6  | 887        | 89.7  | 3,296       | 95.7  |                                                            |       | 49,740                                              | 94.8  |
| Patients identified Jul 2012 - Sep 2012 (2012 Q3)            | 326                                                                                                                                | 3.1   | 1,505      | 5.8   | 410     | 5.7   | 235        | 5.4   | 102        | 10.3  | 149         | 4.3   | 2,727                                                      | 100.0 | 2,727                                               | 5.2   |
| Patients with Serious Liver Injury Outcomes*                 | 744                                                                                                                                | 7.0   | 2,010      | 7.8   | 444     | 6.2   | 198        | 4.5   | 53         | 5.4   | 200         | 5.8   | 46                                                         | 1.7   | 3,649                                               | 7.0   |
| ICD-9-CM Diagnosis                                           |                                                                                                                                    |       |            |       |         |       |            |       |            |       |             |       |                                                            |       |                                                     |       |
| 570 Acute and subacute necrosis of liver                     | 23                                                                                                                                 | 3.1   | 103        | 5.1   | 10      | 2.3   | 4          | 2.0   | 2          | 3.8   | 1           | 0.5   | 3                                                          | 6.5   | 143                                                 | 3.9   |
| 571.5 Cirrhosis of liver without mention of alcohol          | 29                                                                                                                                 | 3.9   | 64         | 3.2   | 13      | 2.9   | 4          | 2.0   | 4          | 7.5   | 4           | 2.0   | 1                                                          | 2.2   | 118                                                 | 3.2   |
| 572.2 Hepatic coma                                           | 6                                                                                                                                  | 0.8   | 20         | 1.0   | 4       | 0.9   | -          | 0.0   | 1          | 1.9   | 1           | 0.5   | -                                                          | 0.0   | 32                                                  | 0.9   |
| 572.4 Hepatorenal syndrome                                   | 2                                                                                                                                  | 0.3   | 6          | 0.3   | -       | 0.0   | -          | 0.0   | 1          | 1.9   | -           | 0.0   | -                                                          | 0.0   | 9                                                   | 0.2   |
| 573.0 Chronic passive congestion of liver                    | 3                                                                                                                                  | 0.4   | 24         | 1.2   | 2       | 0.5   | 1          | 0.5   | -          | 0.0   | 2           | 1.0   | 1                                                          | 2.2   | 32                                                  | 0.9   |
| 573.3 Hepatitis, unspecified                                 | 28                                                                                                                                 | 3.8   | 96         | 4.8   | 14      | 3.2   | 7          | 3.5   | 2          | 3.8   | 8           | 4.0   | 2                                                          | 4.3   | 155                                                 | 4.2   |
| 573.8 Other specified disorders of liver                     | 167                                                                                                                                | 22.4  | 366        | 18.2  | 122     | 27.5  | 54         | 27.3  | 8          | 15.1  | 48          | 24.0  | 2                                                          | 4.3   | 765                                                 | 21.0  |
| 573.9 Unspecified disorder of liver                          | 39                                                                                                                                 | 5.2   | 90         | 4.5   | 22      | 5.0   | 10         | 5.1   | 4          | 7.5   | 15          | 7.5   | 1                                                          | 2.2   | 180                                                 | 4.9   |
| 782.4 Jaundice, unspecified                                  | 36                                                                                                                                 | 4.8   | 84         | 4.2   | 19      | 4.3   | 7          | 3.5   | 2          | 3.8   | 11          | 5.5   | 5                                                          | 10.9  | 159                                                 | 4.4   |
| 789.1 Hepatomegaly                                           | 39                                                                                                                                 | 5.2   | 98         | 4.9   | 17      | 3.8   | 13         | 6.6   | -          | 0.0   | 11          | 5.5   | -                                                          | 0.0   | 178                                                 | 4.9   |
| 790.4 Nonspecific elevation of levels of transaminase or LDH | 119                                                                                                                                | 16.0  | 332        | 16.5  | 76      | 17.1  | 38         | 19.2  | 15         | 28.3  | 32          | 16.0  | 6                                                          | 13.0  | 612                                                 | 16.8  |
| 790.5 Other or nonspecified abnormal serum levels            | 163                                                                                                                                | 21.9  | 500        | 24.9  | 118     | 26.6  | 32         | 16.2  | 7          | 13.2  | 42          | 21.0  | 20                                                         | 43.5  | 862                                                 | 23.6  |
| 791.4 Biliruria                                              | 1                                                                                                                                  | 0.1   | 2          | 0.1   | 1       | 0.2   | -          | 0.0   | 1          | 1.9   | 1           | 0.5   | -                                                          | 0.0   | 6                                                   | 0.2   |
| 794.8 Nonspecific abnormal results of liver function test    | 120                                                                                                                                | 16.1  | 301        | 15.0  | 50      | 11.3  | 32         | 16.2  | 8          | 15.1  | 26          | 13.0  | 1                                                          | 2.2   | 537                                                 | 14.7  |
| ICD-9-CM Procedures                                          |                                                                                                                                    |       |            |       |         |       |            |       |            |       |             |       |                                                            |       |                                                     |       |
| 50.11 Closed (percutaneous) [needle] biopsy of liver         | 4                                                                                                                                  | 0.5   | 14         | 0.7   | 3       | 0.7   | 1          | 0.5   | -          | 0.0   | -           | 0.0   | 1                                                          | 2.2   | 22                                                  | 0.6   |
| 50.12 Open biopsy of liver                                   | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | 1           | 0.5   | -                                                          | 0.0   | 1                                                   | 0.0   |
| 50.13 Transjugular liver biopsy                              | -                                                                                                                                  | 0.0   | 2          | 0.1   | 1       | 0.2   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | 3                                                   | 0.1   |
| 50.14 Laparoscopic liver biopsy                              | 4                                                                                                                                  | 0.5   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | 1           | 0.5   | 1                                                          | 2.2   | 5                                                   | 0.1   |
| 50.5 Liver transplant                                        | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| 50.51 Auxiliary liver transplant                             | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| 50.59 Other transplant of liver                              | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| 50.91 Percutaneous aspiration of liver                       | -                                                                                                                                  | 0.0   | 4          | 0.2   | -       | 0.0   | -          | 0.0   | -          | 0.0   | 1           | 0.5   | -                                                          | 0.0   | 5                                                   | 0.1   |
| CPT Procedures                                               |                                                                                                                                    |       |            |       |         |       |            |       |            |       |             |       |                                                            |       |                                                     |       |
| 47000 Biopsy of Liver, Needle: Percutaneous                  | 5                                                                                                                                  | 0.7   | 19         | 0.9   | 4       | 0.9   | 2          | 1.0   | -          | 0.0   | 3           | 1.5   | -                                                          | 0.0   | 33                                                  | 0.9   |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other         | 3                                                                                                                                  | 0.4   | 4          | 0.2   | 1       | 0.2   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | 8                                                   | 0.2   |
| 47100 Biopsy of Liver, Wedge                                 | 1                                                                                                                                  | 0.1   | 1          | 0.0   | -       | 0.0   | 1          | 0.5   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | 3                                                   | 0.1   |
| 47135 Liver allotransplant; orthotopic, partial or whole     | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| 47136 Liver allotransplant; heterotopic, partial or whole    | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| 78205 Liver Imaging (Spect)                                  | -                                                                                                                                  | 0.0   | 1          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | 1           | 0.5   | -                                                          | 0.0   | 2                                                   | 0.0   |
| 78206 Liver imaging (SPECT); with vascular flow              | -                                                                                                                                  | 0.0   | -          | 0.0   | -       | 0.0   | -          | 0.0   | -          | 0.0   | -           | 0.0   | -                                                          | 0.0   | -                                                   | 0.0   |
| Lab Codes                                                    |                                                                                                                                    |       |            |       |         |       |            |       |            |       |             |       |                                                            |       |                                                     |       |
| 1742-6 Elevation of alanine transaminase levels, 3x higher   | 9                                                                                                                                  | 1.2   | 17         | 0.8   | 2       | 0.5   | 4          | 2.0   | 3          | 5.7   | -           | 0.0   | 15                                                         | 32.6  | 35                                                  | 1.0   |
| 1920-8 Elevation of aspartate transaminase levels, 3x higher | 9                                                                                                                                  | 1.2   | 12         | 0.6   | -       | 0.0   | 2          | 1.0   | 2          | 3.8   | -           | 0.0   | 12                                                         | 26.1  | 25                                                  | 0.7   |
| 1975-2 Elevation of bilirubin level, 1.5x higher             | 4                                                                                                                                  | 0.5   | 8          | 0.4   | -       | 0.0   | -          | 0.0   | 3          | 5.7   | -           | 0.0   | 5                                                          | 10.9  | 15                                                  | 0.4   |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

**Table 3. Number of Patients Diagnosed with Interstitial Lung Disease, by Cohort and Period, US DoD Database: July 1, 2009 - September 30, 2012**

| US DoD Database Surveillance                                       | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period (Jul 2009 - Sep 2012) |       |            |       |         |       |            |       |            |       |             |       | Identified in<br>Current Quarter<br>Only (Jul-Sep<br>2012) |       | Cumulative ILD<br>Total<br>(Jul 2009 - Sep<br>2012) |       |
|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|------------------------------------------------------------|-------|-----------------------------------------------------|-------|
|                                                                    | Dronedarone                                                                                                           |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       |                                                            |       |                                                     |       |
|                                                                    | N                                                                                                                     | %     | N          | %     | N       | %     | N          | %     | N          | %     | N           | %     | N                                                          | %     | N                                                   | %     |
| Total patients identified through 2012 Q3                          | 10,624                                                                                                                | 100.0 | 25,826     | 100.0 | 7,196   | 100.0 | 4,387      | 100.0 | 989        | 100.0 | 3,445       | 100.0 |                                                            |       | 52,467                                              | 100.0 |
| Patients identified prior to 2012 Q3                               | 10,298                                                                                                                | 96.9  | 24,321     | 94.2  | 6,786   | 94.3  | 4,152      | 94.6  | 887        | 89.7  | 3,296       | 95.7  |                                                            |       | 49,740                                              | 94.8  |
| Patients identified Jul 2012 - Sep 2012 (2012 Q3)                  | 326                                                                                                                   | 3.1   | 1,505      | 5.8   | 410     | 5.7   | 235        | 5.4   | 102        | 10.3  | 149         | 4.3   | 2,727                                                      | 100.0 | 2,727                                               | 5.2   |
| Patients with Interstitial Lung Disease Outcomes*                  | 346                                                                                                                   | 3.3   | 1,077      | 4.2   | 212     | 2.9   | 85         | 1.9   | 34         | 3.4   | 97          | 2.8   | 13                                                         | 0.5   | 1,851                                               | 3.5   |
| 495.9 Unspecified allergic alveolitis and pneumonitis              | 2                                                                                                                     | 0.6   | 14         | 0.9   | 2       | 0.5   | 0          | 0.0   | 0          | 0.0   | 2           | 1.3   | -                                                          | 0.0   | 20                                                  | 1.1   |
| 515 Postinflammatory pulmonary fibrosis                            | 293                                                                                                                   | 89.9  | 917        | 60.9  | 187     | 45.6  | 74         | 31.5  | 32         | 31.4  | 85          | 57.0  | 13                                                         | 100.0 | 1,588                                               | 85.8  |
| 516.3 Idiopathic fibrosing alveolitis                              | 18                                                                                                                    | 5.5   | 43         | 2.9   | 7       | 1.7   | 2          | 0.9   | 0          | 0.0   | 3           | 2.0   | -                                                          | 0.0   | 73                                                  | 3.9   |
| 516.8 Other specified alveolar and parietoalveolar pneumonopathies | 14                                                                                                                    | 4.3   | 48         | 3.2   | 9       | 2.2   | 6          | 2.6   | 2          | 2.0   | 2           | 1.3   | -                                                          | 0.0   | 81                                                  | 4.4   |
| 516.9 Unspecified alveolar and parietoalveolar pneumonopathy       | 19                                                                                                                    | 5.8   | 66         | 4.4   | 8       | 2.0   | 4          | 1.7   | 0          | 0.0   | 5           | 3.4   | -                                                          | 0.0   | 102                                                 | 5.5   |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

Next quarter we will capture the following codes:

- 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
- 516.31 Idiopathic pulmonary fibrosis (IPF)
- 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
- 516.33 Acute interstitial pneumonitis (AIP)
- 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
- 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
- 516.36 Cryptogenic organizing pneumonia (COP)
- 516.37 Desquamative interstitial pneumonia (DIP)

Table 4. Age / Gender Demographics for by Drug Cohort, US DoD Database, July 1, 2009 to Sep 2012

| Age Group / Gender    | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide |              | Propafenone  |              | Total         |              |
|-----------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|------------|--------------|--------------|--------------|---------------|--------------|
|                       | N             | %            | N             | %            | N            | %            | N            | %            | N          | %            | N            | %            | N             | %            |
| <b>Total Patients</b> | <b>10,624</b> | <b>100.0</b> | <b>25,826</b> | <b>100.0</b> | <b>7,196</b> | <b>100.0</b> | <b>4,387</b> | <b>100.0</b> | <b>989</b> | <b>100.0</b> | <b>3,445</b> | <b>100.0</b> | <b>52,467</b> | <b>100.0</b> |
| < 18                  | 0             | 0.0          | 6             | 0.0          | 4            | 0.1          | 3            | 0.1          | 0          | 0.0          | 1            | 0.0          | 14            | 0.0          |
| 18-24                 | 5             | 0.0          | 9             | 0.0          | 7            | 0.1          | 36           | 0.8          | 2          | 0.2          | 8            | 0.2          | 67            | 0.1          |
| 25-34                 | 31            | 0.3          | 27            | 0.1          | 28           | 0.4          | 110          | 2.5          | 5          | 0.5          | 37           | 1.1          | 238           | 0.5          |
| 35-44                 | 109           | 1.0          | 82            | 0.3          | 58           | 0.8          | 199          | 4.5          | 8          | 0.8          | 77           | 2.2          | 533           | 1.0          |
| 45-54                 | 426           | 4.0          | 517           | 2.0          | 258          | 3.6          | 388          | 8.8          | 48         | 4.9          | 238          | 6.9          | 1,875         | 3.6          |
| 55-64                 | 1,596         | 15.0         | 2,782         | 10.8         | 1,067        | 14.8         | 875          | 19.9         | 191        | 19.3         | 624          | 18.1         | 7,135         | 13.6         |
| 65-74                 | 3,836         | 36.1         | 8,109         | 31.4         | 2,552        | 35.5         | 1,524        | 34.7         | 398        | 40.2         | 1,216        | 35.3         | 17,635        | 33.6         |
| 75-84                 | 3,671         | 34.6         | 10,437        | 40.4         | 2,536        | 35.2         | 1,027        | 23.4         | 295        | 29.8         | 982          | 28.5         | 18,948        | 36.1         |
| 85+                   | 950           | 8.9          | 3,857         | 14.9         | 686          | 9.5          | 225          | 5.1          | 42         | 4.2          | 262          | 7.6          | 6,022         | 11.5         |

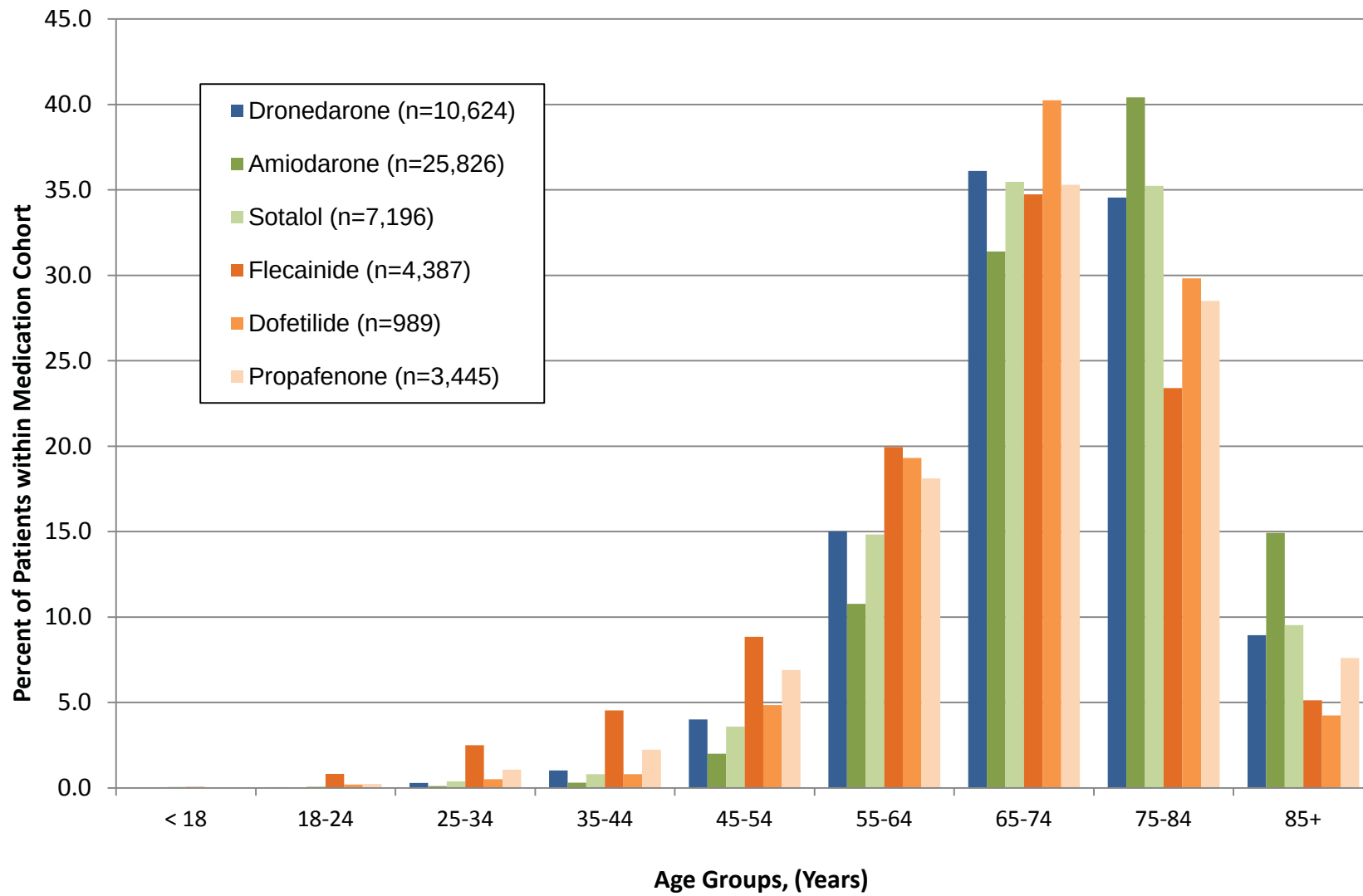
|               |              |             |               |             |              |             |              |             |            |             |              |             |               |             |
|---------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
| <b>Female</b> | <b>4,800</b> | <b>45.2</b> | <b>10,019</b> | <b>38.8</b> | <b>3,253</b> | <b>45.2</b> | <b>2,209</b> | <b>50.4</b> | <b>335</b> | <b>33.9</b> | <b>1,727</b> | <b>50.1</b> | <b>22,343</b> | <b>42.6</b> |
| < 18          | 0            | 0.0         | 3             | 0.0         | 2            | 0.1         | 1            | 0.0         | 0          | 0.0         | 1            | 0.1         | 7             | 0.0         |
| 18-24         | 1            | 0.0         | 0             | 0.0         | 5            | 0.2         | 7            | 0.3         | 2          | 0.6         | 3            | 0.2         | 18            | 0.1         |
| 25-34         | 6            | 0.1         | 7             | 0.1         | 15           | 0.5         | 37           | 1.7         | 2          | 0.6         | 8            | 0.5         | 75            | 0.3         |
| 35-44         | 24           | 0.5         | 17            | 0.2         | 24           | 0.7         | 51           | 2.3         | 1          | 0.3         | 13           | 0.8         | 130           | 0.6         |
| 45-54         | 121          | 2.5         | 129           | 1.3         | 69           | 2.1         | 124          | 5.6         | 11         | 3.3         | 78           | 4.5         | 532           | 2.4         |
| 55-64         | 595          | 12.4        | 759           | 7.6         | 338          | 10.4        | 379          | 17.2        | 50         | 14.9        | 246          | 14.2        | 2,367         | 10.6        |
| 65-74         | 1,657        | 34.5        | 2,788         | 27.8        | 1,093        | 33.6        | 806          | 36.5        | 129        | 38.5        | 628          | 36.4        | 7,101         | 31.8        |
| 75-84         | 1,835        | 38.2        | 4,297         | 42.9        | 1,282        | 39.4        | 641          | 29.0        | 119        | 35.5        | 569          | 32.9        | 8,743         | 39.1        |
| 85+           | 561          | 11.7        | 2,019         | 20.2        | 425          | 13.1        | 163          | 7.4         | 21         | 6.3         | 181          | 10.5        | 3,370         | 15.1        |

|             |              |             |               |             |              |             |              |             |            |             |              |             |               |             |
|-------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
| <b>Male</b> | <b>5,824</b> | <b>54.8</b> | <b>15,807</b> | <b>61.2</b> | <b>3,943</b> | <b>54.8</b> | <b>2,178</b> | <b>49.6</b> | <b>653</b> | <b>66.0</b> | <b>1,718</b> | <b>49.9</b> | <b>30,123</b> | <b>57.4</b> |
| Male <18    | 0            | .           | 3             | 0.0         | 2            | 0.1         | 2            | 0.1         | 0          | 0.0         | 0            | 0.0         | 7             | 0.0         |
| Male 18-24  | 4            | 0.1         | 9             | 0.1         | 2            | 0.1         | 29           | 1.3         | 0          | 0.0         | 5            | 0.3         | 49            | 0.2         |
| Male 25-34  | 25           | 0.4         | 20            | 0.1         | 13           | 0.3         | 73           | 3.4         | 3          | 0.5         | 29           | 1.7         | 163           | 0.5         |
| Male 35-44  | 85           | 1.5         | 65            | 0.4         | 34           | 0.9         | 148          | 6.8         | 7          | 1.1         | 64           | 3.7         | 403           | 1.3         |
| Male 45-54  | 305          | 5.2         | 388           | 2.5         | 189          | 4.8         | 264          | 12.1        | 37         | 5.7         | 160          | 9.3         | 1,343         | 4.5         |
| Male 55-64  | 1,001        | 17.2        | 2,023         | 12.8        | 729          | 18.5        | 496          | 22.8        | 141        | 21.6        | 378          | 22.0        | 4,768         | 15.8        |
| Male 65-74  | 2,179        | 37.4        | 5,321         | 33.7        | 1,459        | 37.0        | 718          | 33.0        | 268        | 41.0        | 588          | 34.2        | 10,533        | 35.0        |
| Male 75-84  | 1,836        | 31.5        | 6,140         | 38.8        | 1,254        | 31.8        | 386          | 17.7        | 176        | 27.0        | 413          | 24.0        | 10,205        | 33.9        |
| Male 85+    | 389          | 6.7         | 1,838         | 11.6        | 261          | 6.6         | 62           | 2.8         | 21         | 3.2         | 81           | 4.7         | 2,652         | 8.8         |

|               |   |     |   |     |   |     |   |     |   |     |   |     |   |     |
|---------------|---|-----|---|-----|---|-----|---|-----|---|-----|---|-----|---|-----|
| Unknown 65-74 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.1 | 0 | 0.0 | 1 | 0.0 |
|---------------|---|-----|---|-----|---|-----|---|-----|---|-----|---|-----|---|-----|



**Figure 1. Age Demographics of Study Medication Cohorts by Index Drug;  
US DoD Database: July 2009 - September 2012**





**Tabel 1. Patients with a Study Drug of Interest between 7/20/2009 and 12/31/2012, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Description                                                              | Dronedarone   |             | Amiodarone    |             | Sotalol       |             | Flecainide    |             | Dofetilide   |             | Propafenone   |             | Total          |             |
|--------------------------------------------------------------------------|---------------|-------------|---------------|-------------|---------------|-------------|---------------|-------------|--------------|-------------|---------------|-------------|----------------|-------------|
|                                                                          | N             | %           | N             | %           | N             | %           | N             | %           | N            | %           | N             | %           | N              | %           |
| <b>Assign the first study drug as the cohort</b>                         | <b>13,205</b> | <b>100</b>  | <b>58,535</b> | <b>100</b>  | <b>23,234</b> | <b>100</b>  | <b>13,006</b> | <b>100</b>  | <b>2,660</b> | <b>100</b>  | <b>10,366</b> | <b>100</b>  | <b>121,006</b> | <b>100</b>  |
| <i>Less patients without 365 days of eligibility* prior to indexdate</i> | 182           | 1.4         | 562           | 1.0         | 528           | 2.3         | 478           | 3.7         | 63           | 2.4         | 235           | 2.3         | 2,048          | 1.7         |
| Remaining patients                                                       | 13,023        | 98.6        | 57,973        | 99.0        | 22,706        | 97.7        | 12,528        | 96.3        | 2,597        | 97.6        | 10,131        | 97.7        | 118,958        | 98.3        |
| <i>Less patients without AF in the year prior to indexdate</i>           | 1,882         | 14.3        | 15,855        | 27.1        | 5,527         | 23.8        | 3,603         | 27.7        | 278          | 10.5        | 2,362         | 22.8        | 29,507         | 24.4        |
| Remaining patients                                                       | 11,141        | 84.4        | 42,118        | 72.0        | 17,179        | 73.9        | 8,925         | 68.6        | 2,319        | 87.2        | 7,769         | 74.9        | 89,451         | 73.9        |
| <i>Less patients with the index drug in the year prior to indexdate</i>  | 0             | 0.0         | 13,989        | 23.9        | 9,384         | 40.4        | 4,025         | 30.9        | 1,306        | 49.1        | 4,045         | 39.0        | 32,749         | 27.1        |
| Remaining patients                                                       | 11,141        | 84.4        | 28,129        | 48.1        | 7,795         | 33.5        | 4,900         | 37.7        | 1,013        | 38.1        | 3,724         | 35.9        | 56,702         | 46.9        |
| <i>Less patients with multiple study drugs on index date</i>             | 2             | 0.0         | 23            | 0.0         | 0             | 0.0         | 3             | 0.0         | 0            | 0.0         | 3             | 0.0         | 31             | 0.0         |
| Remaining patients                                                       | 11,139        | 84.4        | 28,106        | 48.0        | 7,795         | 33.5        | 4,897         | 37.7        | 1,013        | 38.1        | 3,721         | 35.9        | 56,671         | 46.8        |
| <i>Less patients with date of death preceding index date</i>             | 1             | 0.0         | 0             | 0.0         | 0             | 0.0         | 1             | 0.0         | 0            | 0.0         | 0             | 0.0         | 2              | 0.0         |
| <b>Patients in cohort</b>                                                | <b>11,138</b> | <b>84.3</b> | <b>28,106</b> | <b>48.0</b> | <b>7,795</b>  | <b>33.5</b> | <b>4,896</b>  | <b>37.6</b> | <b>1,013</b> | <b>38.1</b> | <b>3,721</b>  | <b>35.9</b> | <b>56,669</b>  | <b>46.8</b> |

\* Degge received a refreshed eligibility record file from Health ResearchTX that contained updated eligibility records from July 2009 through December 2012. Previously, only quarterly eligibility status by month was provided for each quarterly update; changes in eligibility status in previous quarters was not provided.

**Table 2. Number of Patients Diagnosed with Serious Liver Injury, by Cohort and Period, US DoD Database: 7/20/2009 - 12/31/2012 \***

| US DOD Surveillance from 7/20/2009 - 12/31/2012                        | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Current Quarter Only |            | Total         |            |
|------------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|----------------------|------------|---------------|------------|
|                                                                        | N             | %          | N             | %          | N            | %          | N            | %          | N            | %          | N            | %          | N                    | %          | N             | %          |
| <b>Total patients identified through 2012 Q4</b>                       | <b>11,138</b> | <b>100</b> | <b>28,106</b> | <b>100</b> | <b>7,795</b> | <b>100</b> | <b>4,896</b> | <b>100</b> | <b>1,013</b> | <b>100</b> | <b>3,721</b> | <b>100</b> |                      |            | <b>56,669</b> | <b>100</b> |
| Patients identified prior to 2012 Q3                                   | 10,624        | 95.4       | 25,826        | 91.9       | 7,196        | 92.3       | 4,387        | 89.6       | 989          | 97.6       | 3,445        | 92.6       |                      |            | 52,467        | 92.6       |
| <b>Patients identified in current quarter Oct 2012 - Dec 2012 (Q4)</b> | <b>423</b>    | <b>3.8</b> | <b>2,017</b>  | <b>7.2</b> | <b>535</b>   | <b>6.9</b> | <b>375</b>   | <b>7.7</b> | <b>73</b>    | <b>7.2</b> | <b>208</b>   | <b>5.6</b> | <b>3,631</b>         | <b>100</b> | <b>3,631</b>  | <b>6.4</b> |
| Patients with ≥1 Serious Liver Injury Outcomes Definition Code†        | 878           | 7.9        | 2,371         | 8.4        | 541          | 6.9        | 250          | 5.1        | 66           | 6.5        | 241          | 6.5        | 698                  | 19.2       | 4,347         | 7.7        |
| <b>ICD-9-CM Diagnosis</b>                                              |               |            |               |            |              |            |              |            |              |            |              |            |                      |            |               |            |
| 570 Acute and Subacute Necrosis of Liver                               | 24            | 2.7        | 121           | 5.1        | 11           | 2.0        | 5            | 2.0        | 2            | 3.0        | 1            | 0.4        | 21                   | 3.0        | 164           | 3.8        |
| 571.5 Cirrhosis Of Liver without Mention of Alcohol                    | 31            | 3.5        | 81            | 3.4        | 15           | 2.8        | 4            | 1.6        | 5            | 7.6        | 6            | 2.5        | 24                   | 3.4        | 142           | 3.3        |
| 572.2 Hepatic Coma                                                     | 7             | 0.8        | 25            | 1.1        | 4            | 0.7        | -            | 0.0        | 1            | 1.5        | 1            | 0.4        | 6                    | 0.9        | 38            | 0.9        |
| 572.4 Hepatorenal Syndrome                                             | 2             | 0.2        | 10            | 0.4        | -            | 0.0        | -            | 0.0        | 1            | 1.5        | -            | 0.0        | 4                    | 0.6        | 13            | 0.3        |
| 573.0 Chronic Passive Congestion Of Liver                              | 3             | 0.3        | 25            | 1.1        | 2            | 0.4        | 2            | 0.8        | -            | 0.0        | 2            | 0.8        | 2                    | 0.3        | 34            | 0.8        |
| 573.3 Hepatitis, Unspecified                                           | 32            | 3.6        | 107           | 4.5        | 16           | 3.0        | 8            | 3.2        | 2            | 3.0        | 10           | 4.1        | 20                   | 2.9        | 175           | 4.0        |
| 573.4 Hepatic Infarction                                               | -             | 0.0        | 1             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | 1             | 0.0        |
| 573.8 Other Specified Disrdrs of Liver                                 | 202           | 23.0       | 431           | 18.2       | 140          | 25.9       | 66           | 26.4       | 12           | 18.2       | 56           | 23.2       | 142                  | 20.3       | 907           | 20.9       |
| 573.9 Unspecified Disorder of the Liver                                | 44            | 5.0        | 111           | 4.7        | 28           | 5.2        | 14           | 5.6        | 5            | 7.6        | 19           | 7.9        | 41                   | 5.9        | 221           | 5.1        |
| 782.4 Jaundice, Unspecified                                            | 44            | 5.0        | 98            | 4.1        | 24           | 4.4        | 7            | 2.8        | 1            | 1.5        | 11           | 4.6        | 26                   | 3.7        | 185           | 4.3        |
| 789.1 Hepatomegaly                                                     | 44            | 5.0        | 110           | 4.6        | 20           | 3.7        | 18           | 7.2        | 1            | 1.5        | 14           | 5.8        | 29                   | 4.2        | 207           | 4.8        |
| 790.4 Nonspecific Elevation of Levels of Transaminase Or Ldh           | 140           | 15.9       | 392           | 16.5       | 85           | 15.7       | 50           | 20.0       | 16           | 24.2       | 36           | 14.9       | 107                  | 15.3       | 719           | 16.5       |
| 790.5 Other Or Nonspecified Abnormal Serum Levels                      | 201           | 22.9       | 593           | 25.0       | 150          | 27.7       | 41           | 16.4       | 11           | 16.7       | 50           | 20.7       | 184                  | 26.4       | 1,046         | 24.1       |
| 791.4 Biluria                                                          | 1             | 0.1        | 3             | 0.1        | 1            | 0.2        | -            | 0.0        | 1            | 1.5        | 2            | 0.8        | 2                    | 0.3        | 8             | 0.2        |
| 794.8 Nonspecific Abnormal Results of Liver Function Test              | 137           | 15.6       | 357           | 15.1       | 66           | 12.2       | 41           | 16.4       | 9            | 13.6       | 34           | 14.1       | 107                  | 15.3       | 644           | 14.8       |
| <b>ICD-9-CM Procedures</b>                                             |               |            |               |            |              |            |              |            |              |            |              |            |                      |            |               |            |
| 50.11 Closed (Percutaneous) [needle] Biopsy of Liver                   | 5             | 0.6        | 14            | 0.6        | 3            | 0.6        | 1            | 0.4        | -            | 0.0        | 1            | 0.4        | 2                    | 0.3        | 24            | 0.6        |
| 50.12 Open Biopsy of Liver                                             | -             | 0.0        | -             | 0.0        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | 1                    | 0.1        | 2             | 0.0        |
| 50.13 Transjugular Liver Biopsy                                        | -             | 0.0        | 2             | 0.1        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | 3             | 0.1        |
| 50.14 Laparoscopic Liver Biopsy                                        | 4             | 0.5        | -             | 0.0        | -            | 0.0        | 1            | 0.4        | -            | 0.0        | 1            | 0.4        | 1                    | 0.1        | 6             | 0.1        |
| 50.5 Liver transplant                                                  | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 50.51 Auxiliary liver transplant                                       | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 50.59 Other transplant of liver                                        | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 50.91 Percutaneous Aspiration of Liver                                 | -             | 0.0        | 4             | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | -                    | 0.0        | 5             | 0.1        |
| <b>CPT Procedures</b>                                                  |               |            |               |            |              |            |              |            |              |            |              |            |                      |            |               |            |
| 47000 Biopsy of Liver, Needle: Percutaneous                            | 7             | 0.8        | 24            | 1.0        | 5            | 0.9        | 2            | 0.8        | -            | 0.0        | 3            | 1.2        | 8                    | 1.1        | 41            | 0.9        |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other                   | 3             | 0.3        | 4             | 0.2        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | 8             | 0.2        |
| 47100 Biopsy of Liver, wedge                                           | 2             | 0.2        | 3             | 0.1        | 1            | 0.2        | 2            | 0.8        | 1            | 1.5        | -            | 0.0        | 6                    | 0.9        | 9             | 0.2        |
| 47135 Liver allotransplant; orthotopic, partial or whole               | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 47136 Liver allotransplant; heterotopic, partial or whole              | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 78205 Liver Imaging (Spect)                                            | -             | 0.0        | 1             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | -                    | 0.0        | 2             | 0.0        |
| 78206 Liver imaging (SPECT); with vascular flow                        | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| <b>Lab Results</b>                                                     |               |            |               |            |              |            |              |            |              |            |              |            |                      |            |               |            |
| 1742-6 Alanine Aminotransferase                                        | 13            | 1.5        | 16            | 0.7        | 2            | 0.4        | 3            | 1.2        | 1            | 1.5        | 1            | 0.4        | 1                    | 0.1        | 36            | 0.8        |
| 1920-8 Aspartate Aminotransferase                                      | 12            | 1.4        | 11            | 0.5        | 1            | 0.2        | 2            | 0.8        | -            | 0.0        | -            | 0.0        | 1                    | 0.1        | 26            | 0.6        |
| 1975-2 Bilirubin                                                       | 3             | 0.3        | 7             | 0.3        | 1            | 0.2        | 1            | 0.4        | 1            | 1.5        | -            | 0.0        | -2                   | -0.3       | 13            | 0.3        |

\* Outcomes identified from "Refreshed Eligibility" data.

† Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

**Table 3. Number of Patients Diagnosed with Interstitial Lung Disease, by Cohort and Period, US DoD Database: 7/20/2009 - 12/31/2012 \***

| US DOD Surveillance from 7/20/2009 - 12/31/2012                                             | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Current Quarter Only |             | Total         |            |
|---------------------------------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|----------------------|-------------|---------------|------------|
|                                                                                             | N             | %          | N             | %          | N            | %          | N            | %          | N            | %          | N            | %          | N                    | %           | N             | %          |
| <b>Total patients identified through 2012 Q4</b>                                            | <b>11,138</b> | <b>100</b> | <b>28,106</b> | <b>100</b> | <b>7,795</b> | <b>100</b> | <b>4,896</b> | <b>100</b> | <b>1,013</b> | <b>100</b> | <b>3,721</b> | <b>100</b> |                      |             | <b>56,669</b> | <b>100</b> |
| Patients identified prior to 2012 Q4                                                        | 10,624        | 95.4       | 25,826        | 91.9       | 7,196        | 92.3       | 4,387        | 89.6       | 989          | 97.6       | 3,445        | 92.6       |                      |             | 52,467        | 92.6       |
| <b>Patients identified in current quarter Oct 2012 - Dec 2012 (Q4)</b>                      | <b>423</b>    | <b>3.8</b> | <b>2,017</b>  | <b>7.2</b> | <b>535</b>   | <b>6.9</b> | <b>375</b>   | <b>7.7</b> | <b>73</b>    | <b>7.2</b> | <b>208</b>   | <b>5.6</b> | <b>3,631</b>         | <b>100</b>  | <b>3,631</b>  | <b>6.4</b> |
| <b>Patients with <math>\geq 1</math> Interstitial Lung Disease Outcome Definition Code†</b> | <b>402</b>    | <b>3.6</b> | <b>1,304</b>  | <b>4.6</b> | <b>262</b>   | <b>3.4</b> | <b>104</b>   | <b>2.1</b> | <b>38</b>    | <b>3.8</b> | <b>116</b>   | <b>3.1</b> | <b>375</b>           | <b>10.3</b> | <b>2,226</b>  | <b>3.9</b> |
| 495.9 Unspecified Allergic Alveolitis and Pneumonitis                                       | 3             | 0.7        | 19            | 1.5        | 4            | 1.5        | 1            | 1.0        | 1            | 2.6        | 3            | 2.6        | 11                   | 2.9         | 31            | 1.4        |
| 515 Postinflammatory Pulmonary Fibrosis                                                     | 335           | 83.3       | 1,090         | 83.6       | 231          | 88.2       | 89           | 85.6       | 35           | 92.1       | 101          | 87.1       | 293                  | 78.1        | 1,881         | 84.5       |
| 516.3 Idiopathic Fibrosing Alveolitis                                                       | 18            | 4.5        | 43            | 3.3        | 7            | 2.7        | 2            | 1.9        | -            | 0.0        | 3            | 2.6        | 0                    | 0.0         | 73            | 3.3        |
| 516.30 Idiopathic Interstitial Pneumonia Unspec                                             | 3             | 0.7        | 12            | 0.9        | 3            | 1.1        | -            | 0.0        | -            | 0.0        | 1            | 0.9        | 19                   | 5.1         | 19            | 0.9        |
| 516.31 Idiopathic Pulmonary Fibrosis                                                        | 6             | 1.5        | 21            | 1.6        | 3            | 1.1        | 2            | 1.9        | -            | 0.0        | 2            | 1.7        | 34                   | 9.1         | 34            | 1.5        |
| 516.32 Idiopathic Interstitial Pneumonitis                                                  | -             | 0.0        | 1             | 0.1        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1                    | 0.3         | 1             | 0.0        |
| 516.33 Acute Interstitial Pneumonitis                                                       | 2             | 0.5        | 1             | 0.1        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 3                    | 0.8         | 3             | 0.1        |
| 516.34 Bronchiolitis Interstitial Lung Dis                                                  | 1             | 0.2        | 4             | 0.3        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 5                    | 1.3         | 5             | 0.2        |
| 516.35 Idiopathic Lymphoid Interstitial Pneumonia                                           | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 516.36 Cryptogenic Organizing Pneumonia                                                     | 1             | 0.2        | 3             | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 4                    | 1.1         | 4             | 0.2        |
| 516.37 Desquamative Interstitial Pneumonia                                                  | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 516.8 Other Specified Alveolar and Parietoalveolar Pneumonopathies                          | 14            | 3.5        | 59            | 4.5        | 9            | 3.4        | 9            | 8.7        | 2            | 5.3        | 2            | 1.7        | 14                   | 3.7         | 95            | 4.3        |
| 516.9 Unspecified Alveolar and Parietoalveolar Pneumonopathy                                | 19            | 4.7        | 67            | 5.1        | 8            | 3.1        | 4            | 3.8        | -            | 0.0        | 5            | 4.3        | 1                    | 0.3         | 103           | 4.6        |

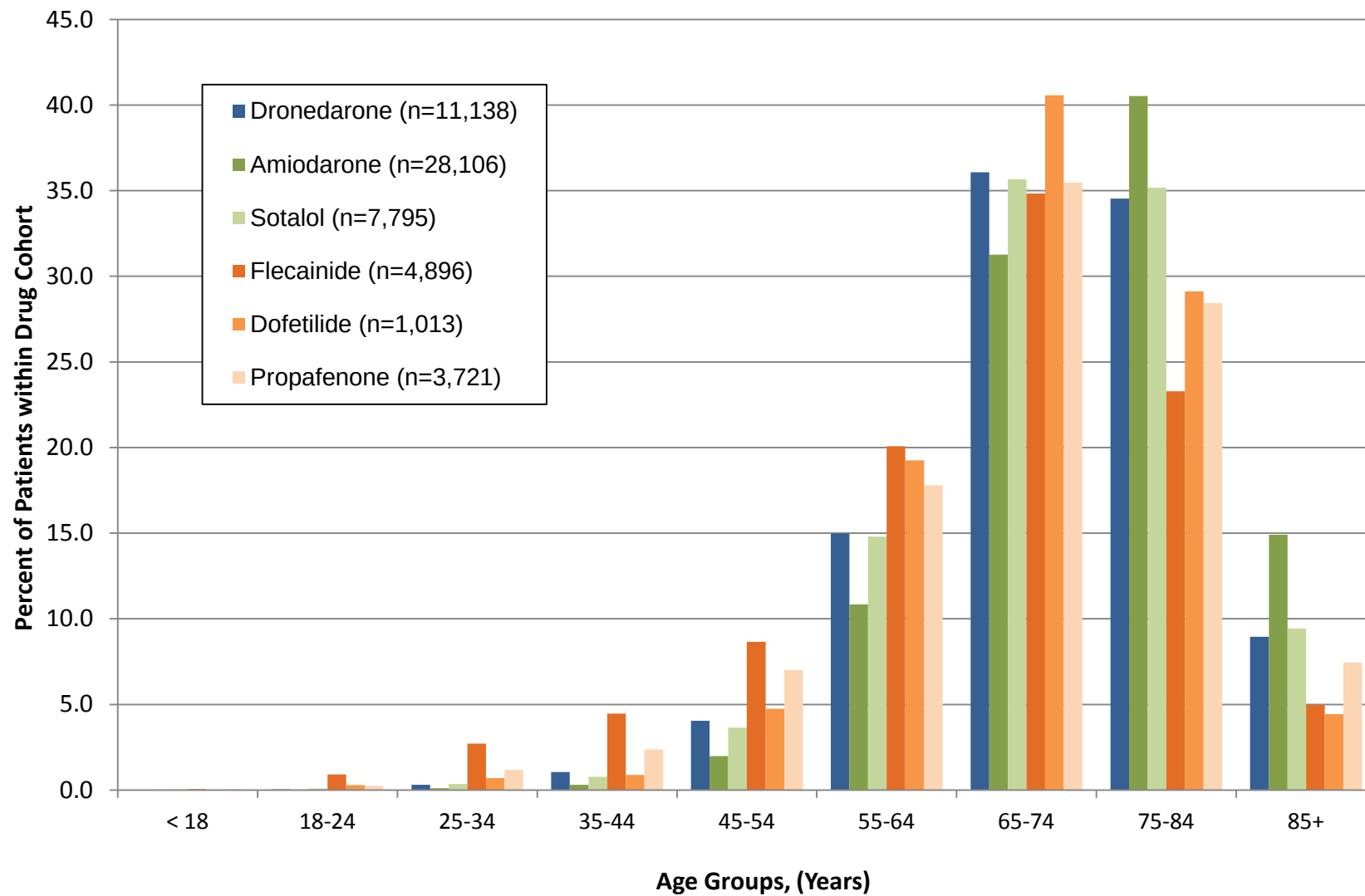
\* Outcomes identified from "Refreshed Eligibility" data.

† Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

**Table 4. Age / Gender Demographics by Drug Cohort, US DoD Database: 7/20/2009 - 12/31/2012**

| Gender / Age Group | Dronedarone   |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide   |             | Propafenone  |             | Total         |             |
|--------------------|---------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|--------------|-------------|--------------|-------------|---------------|-------------|
|                    | N             | %           | N             | %           | N            | %           | N            | %           | N            | %           | N            | %           | N             | %           |
| <b>Total</b>       | <b>11,138</b> | <b>100</b>  | <b>28,106</b> | <b>100</b>  | <b>7,795</b> | <b>100</b>  | <b>4,896</b> | <b>100</b>  | <b>1,013</b> | <b>100</b>  | <b>3,721</b> | <b>100</b>  | <b>56,669</b> | <b>100</b>  |
| < 18               | -             | 0.0         | 6             | 0.0         | 4            | 0.1         | 3            | 0.1         | -            | 0.0         | 2            | 0.1         | 15            | 0.0         |
| 18-24              | 5             | 0.0         | 10            | 0.0         | 7            | 0.1         | 45           | 0.9         | 3            | 0.3         | 9            | 0.2         | 79            | 0.1         |
| 25-34              | 34            | 0.3         | 28            | 0.1         | 28           | 0.4         | 133          | 2.7         | 7            | 0.7         | 44           | 1.2         | 274           | 0.5         |
| 35-44              | 117           | 1.1         | 85            | 0.3         | 60           | 0.8         | 219          | 4.5         | 9            | 0.9         | 88           | 2.4         | 578           | 1.0         |
| 45-54              | 451           | 4.0         | 559           | 2.0         | 284          | 3.6         | 424          | 8.7         | 48           | 4.7         | 261          | 7.0         | 2,027         | 3.6         |
| 55-64              | 1,669         | 15.0        | 3,048         | 10.8        | 1,154        | 14.8        | 983          | 20.1        | 195          | 19.2        | 662          | 17.8        | 7,711         | 13.6        |
| 65-74              | 4,018         | 36.1        | 8,787         | 31.3        | 2,781        | 35.7        | 1,705        | 34.8        | 411          | 40.6        | 1,320        | 35.5        | 19,022        | 33.6        |
| 75-84              | 3,847         | 34.5        | 11,392        | 40.5        | 2,742        | 35.2        | 1,140        | 23.3        | 295          | 29.1        | 1,058        | 28.4        | 20,474        | 36.1        |
| 85+                | 997           | 9.0         | 4,191         | 14.9        | 735          | 9.4         | 244          | 5.0         | 45           | 4.4         | 277          | 7.4         | 6,489         | 11.5        |
| <b>Females</b>     | <b>5,016</b>  | <b>45.0</b> | <b>10,877</b> | <b>38.7</b> | <b>3,521</b> | <b>45.2</b> | <b>2,463</b> | <b>50.3</b> | <b>350</b>   | <b>34.6</b> | <b>1,862</b> | <b>50.0</b> | <b>24,089</b> | <b>42.5</b> |
| < 18               | -             | 0.0         | 3             | 0.0         | 2            | 0.0         | 1            | 0.0         | -            | 0.0         | 1            | 0.0         | 7             | 0.0         |
| 18-24              | 1             | 0.0         | 1             | 0.0         | 5            | 0.1         | 10           | 0.2         | 3            | 0.3         | 4            | 0.1         | 24            | 0.0         |
| 25-34              | 7             | 0.1         | 7             | 0.0         | 14           | 0.2         | 45           | 0.9         | 3            | 0.3         | 10           | 0.3         | 86            | 0.2         |
| 35-44              | 28            | 0.3         | 18            | 0.1         | 23           | 0.3         | 57           | 1.2         | 1            | 0.1         | 16           | 0.4         | 143           | 0.3         |
| 45-54              | 124           | 1.1         | 136           | 0.5         | 78           | 1.0         | 131          | 2.7         | 12           | 1.2         | 86           | 2.3         | 567           | 1.0         |
| 55-64              | 619           | 5.6         | 830           | 3.0         | 380          | 4.9         | 424          | 8.7         | 51           | 5.0         | 268          | 7.2         | 2,572         | 4.5         |
| 65-74              | 1,736         | 15.6        | 3,023         | 10.8        | 1,178        | 15.1        | 907          | 18.5        | 132          | 13.0        | 677          | 18.2        | 7,653         | 13.5        |
| 75-84              | 1,918         | 17.2        | 4,668         | 16.6        | 1,386        | 17.8        | 709          | 14.5        | 123          | 12.1        | 611          | 16.4        | 9,415         | 16.6        |
| 85+                | 583           | 5.2         | 2,191         | 7.8         | 455          | 5.8         | 179          | 3.7         | 25           | 2.5         | 189          | 5.1         | 3,622         | 6.4         |
| <b>Males</b>       | <b>6,122</b>  | <b>55.0</b> | <b>17,229</b> | <b>61.3</b> | <b>4,274</b> | <b>54.8</b> | <b>2,433</b> | <b>49.7</b> | <b>662</b>   | <b>65.4</b> | <b>1,859</b> | <b>50.0</b> | <b>32,579</b> | <b>57.5</b> |
| < 18               | -             | 0.0         | 3             | 0.0         | 2            | 0.0         | 2            | 0.0         | -            | 0.0         | 1            | 0.0         | 8             | 0.0         |
| 18-24              | 4             | 0.0         | 9             | 0.0         | 2            | 0.0         | 35           | 0.7         | -            | 0.0         | 5            | 0.1         | 55            | 0.1         |
| 25-34              | 27            | 0.2         | 21            | 0.1         | 14           | 0.2         | 88           | 1.8         | 4            | 0.4         | 34           | 0.9         | 188           | 0.3         |
| 35-44              | 89            | 0.8         | 67            | 0.2         | 37           | 0.5         | 162          | 3.3         | 8            | 0.8         | 72           | 1.9         | 435           | 0.8         |
| 45-54              | 327           | 2.9         | 423           | 1.5         | 206          | 2.6         | 293          | 6.0         | 36           | 3.6         | 175          | 4.7         | 1,460         | 2.6         |
| 55-64              | 1,050         | 9.4         | 2,218         | 7.9         | 774          | 9.9         | 559          | 11.4        | 144          | 14.2        | 394          | 10.6        | 5,139         | 9.1         |
| 65-74              | 2,282         | 20.5        | 5,764         | 20.5        | 1,603        | 20.6        | 798          | 16.3        | 278          | 27.4        | 643          | 17.3        | 11,368        | 20.1        |
| 75-84              | 1,929         | 17.3        | 6,724         | 23.9        | 1,356        | 17.4        | 431          | 8.8         | 172          | 17.0        | 447          | 12.0        | 11,059        | 19.5        |
| 85+                | 414           | 3.7         | 2,000         | 7.1         | 280          | 3.6         | 65           | 1.3         | 20           | 2.0         | 88           | 2.4         | 2,867         | 5.1         |
| <b>Unknown</b>     | <b>-</b>      | <b>0.0</b>  | <b>-</b>      | <b>0.0</b>  | <b>-</b>     | <b>0.0</b>  | <b>-</b>     | <b>0.0</b>  | <b>1</b>     | <b>0.1</b>  | <b>-</b>     | <b>0.0</b>  | <b>1</b>      | <b>0.0</b>  |

**Figure 1. Age Demographics of Study Drug Cohorts by Index Drug;  
US DoD Database: July 20, 2009 - December 31, 2012**







**Tabel 1. Patients with a Study Drug of Interest between 7/20/2009 and 03/31/2013, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Description                                                             | Dronedaronone |             | Amiodarone    |             | Sotalol       |             | Flecainide    |             | Dofetilide   |             | Propafenone   |             | Total          |             |
|-------------------------------------------------------------------------|---------------|-------------|---------------|-------------|---------------|-------------|---------------|-------------|--------------|-------------|---------------|-------------|----------------|-------------|
|                                                                         | N             | %           | N             | %           | N             | %           | N             | %           | N            | %           | N             | %           | N              | %           |
| <b>Assign the first study drug as the cohort</b>                        | <b>13,794</b> | <b>100</b>  | <b>61,459</b> | <b>100</b>  | <b>24,025</b> | <b>100</b>  | <b>13,636</b> | <b>100</b>  | <b>2,747</b> | <b>100</b>  | <b>10,658</b> | <b>100</b>  | <b>126,319</b> | <b>100</b>  |
| <i>Less patients without 365 days of eligibility prior to indexdate</i> | 189           | 1.4         | 601           | 1.0         | 570           | 2.4         | 519           | 3.8         | 68           | 2.5         | 251           | 2.4         | 2,198          | 1.7         |
| Remaining patients                                                      | 13,605        | 98.6        | 60,858        | 99.0        | 23,455        | 97.6        | 13,117        | 96.2        | 2,679        | 97.5        | 10,407        | 97.6        | 124,121        | 98.3        |
| <i>Less patients without AF in the year prior to indexdate</i>          | 1,974         | 14.3        | 16,621        | 27.0        | 5,693         | 23.7        | 3,802         | 27.9        | 290          | 10.6        | 2,429         | 22.8        | 30,809         | 24.4        |
| Remaining patients                                                      | 11,631        | 84.3        | 44,237        | 72.0        | 17,762        | 73.9        | 9,315         | 68.3        | 2,389        | 87.0        | 7,978         | 74.9        | 93,312         | 73.9        |
| <i>Less patients with the index drug in the year prior to indexdate</i> | 0             | 0.0         | 13,989        | 22.8        | 9,384         | 39.1        | 4,025         | 29.5        | 1,306        | 47.5        | 4,045         | 38.0        | 32,749         | 25.9        |
| Remaining patients                                                      | 11,631        | 84.3        | 30,248        | 49.2        | 8,378         | 34.9        | 5,290         | 38.8        | 1,083        | 39.4        | 3,933         | 36.9        | 60,563         | 47.9        |
| <i>Less patients with multiple study drugs on index date</i>            | 2             | 0.0         | 26            | 0.0         | 0             | 0.0         | 3             | 0.0         | 0            | 0.0         | 3             | 0.0         | 34             | 0.0         |
| Remaining patients                                                      | 11,629        | 84.3        | 30,222        | 49.2        | 8,378         | 34.9        | 5,287         | 38.8        | 1,083        | 39.4        | 3,930         | 36.9        | 60,529         | 47.9        |
| <i>Less patients with date of death preceding index date</i>            | 3             | 0.0         | 7             | 0.0         | 3             | 0.0         | 2             | 0.0         | 0            | 0.0         | 1             | 0.0         | 16             | 0.0         |
| <b>Patients in cohort</b>                                               | <b>11,626</b> | <b>84.3</b> | <b>30,215</b> | <b>49.2</b> | <b>8,375</b>  | <b>34.9</b> | <b>5,285</b>  | <b>38.8</b> | <b>1,083</b> | <b>39.4</b> | <b>3,929</b>  | <b>36.9</b> | <b>60,513</b>  | <b>47.9</b> |

Table 2. Number of Patients with a Diagnosis Code Meeting the Serious Liver Injury Definition by Study Cohort between 07/20/2009 - 03/31/2013; US DoD Database

| US DoD Surveillance from 7/20/2009 - 3/31/2013                         | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Current Quarter Only |             | Total         |            |
|------------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|----------------------|-------------|---------------|------------|
|                                                                        | N             | %          | N             | %          | N            | %          | N            | %          | N            | %          | N            | %          | N                    | %           | N             | %          |
| <b>Total patients identified through 2013-Q1</b>                       | <b>11,626</b> | <b>100</b> | <b>30,215</b> | <b>100</b> | <b>8,375</b> | <b>100</b> | <b>5,285</b> | <b>100</b> | <b>1,083</b> | <b>100</b> | <b>3,929</b> | <b>100</b> |                      |             | <b>60,513</b> | <b>100</b> |
| Patients identified prior to 2013 Q1                                   | 11,138        | 95.8       | 28,106        | 93.0       | 7,795        | 93.1       | 4,896        | 92.6       | 1,013        | 93.5       | 3,721        | 94.7       |                      |             | 56,669        | 93.6       |
| <b>Patients identified in current quarter Jan 2013 - Mar 2013 (Q1)</b> | <b>488</b>    | <b>4.2</b> | <b>2,109</b>  | <b>7.0</b> | <b>580</b>   | <b>6.9</b> | <b>389</b>   | <b>7.4</b> | <b>70</b>    | <b>6.5</b> | <b>208</b>   | <b>5.3</b> | <b>3,844</b>         | <b>100</b>  | <b>3,844</b>  | <b>6.4</b> |
| <b>Patients with ≥1 Serious Liver Injury Definition Code*</b>          | <b>954</b>    | <b>8.2</b> | <b>2,593</b>  | <b>8.6</b> | <b>609</b>   | <b>7.3</b> | <b>282</b>   | <b>5.3</b> | <b>71</b>    | <b>6.6</b> | <b>258</b>   | <b>6.6</b> | <b>420</b>           | <b>10.9</b> | <b>4,767</b>  | <b>7.9</b> |
| <b>ICD-9-CM Diagnosis</b>                                              |               |            |               |            |              |            |              |            |              |            |              |            |                      |             |               |            |
| 570 Acute and Subacute Necrosis of Liver                               | 28            | 2.9        | 130           | 5.0        | 15           | 2.5        | 10           | 3.5        | 2            | 2.8        | 1            | 0.4        | 22                   | 5.2         | 186           | 3.9        |
| 571.5 Cirrhosis Of Liver without Mention of Alcohol                    | 35            | 3.7        | 91            | 3.5        | 16           | 2.6        | 4            | 1.4        | 5            | 7.0        | 7            | 2.7        | 16                   | 3.8         | 158           | 3.3        |
| 572.2 Hepatic Coma                                                     | 9             | 0.9        | 29            | 1.1        | 5            | 0.8        | -            | 0.0        | 1            | 1.4        | 2            | 0.8        | 8                    | 1.9         | 46            | 1.0        |
| 572.4 Hepatorenal Syndrome                                             | 2             | 0.2        | 10            | 0.4        | -            | 0.0        | -            | 0.0        | 1            | 1.4        | -            | 0.0        | -                    | 0.0         | 13            | 0.3        |
| 573.0 Chronic Passive Congestion Of Liver                              | 3             | 0.3        | 25            | 1.0        | 2            | 0.3        | 2            | 0.7        | -            | 0.0        | 2            | 0.8        | -                    | 0.0         | 34            | 0.7        |
| 573.3 Hepatitis, Unspecified                                           | 34            | 3.6        | 112           | 4.3        | 19           | 3.1        | 8            | 2.8        | 2            | 2.8        | 11           | 4.3        | 11                   | 2.6         | 186           | 3.9        |
| 573.4 Hepatic Infarction                                               | -             | 0.0        | 1             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | 1             | 0.0        |
| 573.8 Other Specified Disorders of Liver                               | 219           | 23.0       | 466           | 18.0       | 154          | 25.3       | 74           | 26.2       | 13           | 18.3       | 59           | 22.9       | 78                   | 18.6        | 985           | 20.7       |
| 573.9 Unspecified Disorder of the Liver                                | 48            | 5.0        | 130           | 5.0        | 30           | 4.9        | 15           | 5.3        | 5            | 7.0        | 21           | 8.1        | 28                   | 6.7         | 249           | 5.2        |
| 782.4 Jaundice, Unspecified                                            | 47            | 4.9        | 113           | 4.4        | 26           | 4.3        | 7            | 2.5        | 1            | 1.4        | 13           | 5.0        | 22                   | 5.2         | 207           | 4.3        |
| 789.1 Hepatomegaly                                                     | 49            | 5.1        | 117           | 4.5        | 21           | 3.4        | 20           | 7.1        | 1            | 1.4        | 14           | 5.4        | 15                   | 3.6         | 222           | 4.7        |
| 790.4 Nonspecific Elevation of Levels of Transaminase Or Ldh           | 154           | 16.1       | 422           | 16.3       | 96           | 15.8       | 56           | 19.9       | 18           | 25.4       | 36           | 14.0       | 63                   | 15.0        | 782           | 16.4       |
| 790.5 Other Or Nonspecific Abnormal Serum Levels                       | 215           | 22.5       | 654           | 25.2       | 169          | 27.8       | 47           | 16.7       | 13           | 18.3       | 56           | 21.7       | 108                  | 25.7        | 1,154         | 24.2       |
| 791.4 Biluria                                                          | 1             | 0.1        | 3             | 0.1        | 1            | 0.2        | -            | 0.0        | 1            | 1.4        | 2            | 0.8        | -                    | 0.0         | 8             | 0.2        |
| 794.8 Nonspecific Abnormal Results of Liver Function Test              | 147           | 15.4       | 385           | 14.8       | 77           | 12.6       | 44           | 15.6       | 9            | 12.7       | 37           | 14.3       | 55                   | 13.1        | 699           | 14.7       |
| <b>ICD-9-CM Procedures</b>                                             |               |            |               |            |              |            |              |            |              |            |              |            |                      |             |               |            |
| 50.11 Closed (Percutaneous) [needle] Biopsy of Liver                   | 5             | 0.5        | 15            | 0.6        | 3            | 0.5        | 1            | 0.4        | -            | 0.0        | 1            | 0.4        | 1                    | 0.2         | 25            | 0.5        |
| 50.12 Open Biopsy of Liver                                             | 1             | 0.1        | -             | 0.0        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | 1                    | 0.2         | 3             | 0.1        |
| 50.13 Transjugular Liver Biopsy                                        | -             | 0.0        | 2             | 0.1        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | 3             | 0.1        |
| 50.14 Laparoscopic Liver Biopsy                                        | 4             | 0.4        | 1             | 0.0        | -            | 0.0        | 1            | 0.4        | 1            | 1.4        | 1            | 0.4        | 2                    | 0.5         | 8             | 0.2        |
| 50.5 Liver transplant                                                  | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 50.51 Auxiliary liver transplant                                       | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 50.59 Other transplant of liver                                        | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 50.91 Percutaneous Aspiration of Liver                                 | -             | 0.0        | 4             | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | -                    | 0.0         | 5             | 0.1        |
| <b>CPT Procedures</b>                                                  |               |            |               |            |              |            |              |            |              |            |              |            |                      |             |               |            |
| 47000 Biopsy of Liver, Needle: Percutaneous                            | 7             | 0.7        | 26            | 1.0        | 6            | 1.0        | 2            | 0.7        | -            | 0.0        | 3            | 1.2        | 3                    | 0.7         | 44            | 0.9        |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other                   | 3             | 0.3        | 4             | 0.2        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | 8             | 0.2        |
| 47100 Biopsy of Liver, wedge                                           | 2             | 0.2        | 4             | 0.2        | 1            | 0.2        | 2            | 0.7        | 1            | 1.4        | -            | 0.0        | 1                    | 0.2         | 10            | 0.2        |
| 47135 Liver allotransplant; orthotopic, partial or whole               | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 47136 Liver allotransplant; heterotopic, partial or whole              | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| 78205 Liver Imaging (Spect)                                            | -             | 0.0        | 1             | 0.0        | 1            | 0.2        | -            | 0.0        | -            | 0.0        | 1            | 0.4        | 1                    | 0.2         | 3             | 0.1        |
| 78206 Liver imaging (SPECT); with vascular flow                        | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0         | -             | 0.0        |
| <b>Lab Results</b>                                                     |               |            |               |            |              |            |              |            |              |            |              |            |                      |             |               |            |
| 1742-6 Alanine Aminotransferase                                        | 13            | 1.4        | 21            | 0.8        | 4            | 0.7        | 4            | 1.4        | 1            | 1.4        | 1            | 0.4        | 8                    | 1.9         | 44            | 0.9        |
| 1920-8 Aspartate Aminotransferase                                      | 12            | 1.3        | 17            | 0.7        | 1            | 0.2        | 2            | 0.7        | -            | 0.0        | -            | 0.0        | 6                    | 1.4         | 32            | 0.7        |
| 1975-2 Bilirubin                                                       | 3             | 0.3        | 8             | 0.3        | 1            | 0.2        | 1            | 0.4        | 1            | 1.4        | -            | 0.0        | 1                    | 0.2         | 14            | 0.3        |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

**Table 3. Number of Patients with a Diagnosis Code Meeting the Interstitial Lung Disease Definition by Study Cohort between 07/20/2009 - 03/31/2013; US DoD Database**

| US DoD Surveillance from 7/20/2009 - 3/31/2013                         | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Current Quarter Only |            | Total         |            |
|------------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|----------------------|------------|---------------|------------|
|                                                                        | N             | %          | N             | %          | N            | %          | N            | %          | N            | %          | N            | %          | N                    | %          | N             | %          |
| <b>Total patients identified through 2013-Q1</b>                       | <b>11,626</b> | <b>100</b> | <b>30,215</b> | <b>100</b> | <b>8,375</b> | <b>100</b> | <b>5,285</b> | <b>100</b> | <b>1,083</b> | <b>100</b> | <b>3,929</b> | <b>100</b> |                      |            | <b>60,513</b> | <b>100</b> |
| Patients identified prior to 2013 Q1                                   | 11,138        | 95.8       | 28,106        | 93.0       | 7,795        | 93.1       | 4,896        | 92.6       | 1,013        | 93.5       | 3,721        | 94.7       |                      |            | 56,669        | 93.6       |
| <b>Patients identified in current quarter Jan 2013 - Mar 2013 (Q1)</b> | <b>488</b>    | <b>4.2</b> | <b>2,109</b>  | <b>7.0</b> | <b>580</b>   | <b>6.9</b> | <b>389</b>   | <b>7.4</b> | <b>70</b>    | <b>6.5</b> | <b>208</b>   | <b>5.3</b> | <b>3,844</b>         | <b>100</b> | <b>3,844</b>  | <b>6.4</b> |
| <b>Patients with ≥1 Interstitial Lung Disease Definition Codes*</b>    | <b>429</b>    | <b>3.7</b> | <b>1,422</b>  | <b>4.7</b> | <b>292</b>   | <b>3.5</b> | <b>124</b>   | <b>2.3</b> | <b>43</b>    | <b>4.0</b> | <b>123</b>   | <b>3.1</b> | <b>207</b>           | <b>5.4</b> | <b>2,433</b>  | <b>4.0</b> |
| 495.9 Unspecified Allergic Alveolitis and Pneumonitis                  | 4             | 0.9        | 20            | 1.4        | 4            | 1.4        | 1            | 0.8        | 1            | 2.3        | 3            | 2.4        | 2                    | 1.0        | 33            | 1.4        |
| 515 Postinflammatory Pulmonary Fibrosis                                | 360           | 83.9       | 1,198         | 84.2       | 257          | 88.0       | 107          | 86.3       | 40           | 93.0       | 107          | 87.0       | 188                  | 90.8       | 2,069         | 85.0       |
| 516.3 Idiopathic Fibrosing Alveolitis                                  | 18            | 4.2        | 43            | 3.0        | 7            | 2.4        | 2            | 1.6        | -            | 0.0        | 3            | 2.4        | 0                    | 0.0        | 73            | 3.0        |
| 516.30 Idiopathic Interstitial Pneumonia Unspec                        | 3             | 0.7        | 12            | 0.8        | 3            | 1.0        | -            | 0.0        | -            | 0.0        | 1            | 0.8        | 0                    | 0.0        | 19            | 0.8        |
| 516.31 Idiopathic Pulmonary Fibrosis                                   | 7             | 1.6        | 25            | 1.8        | 6            | 2.1        | 3            | 2.4        | -            | 0.0        | 2            | 1.6        | 9                    | 4.3        | 43            | 1.8        |
| 516.32 Idiopathic Interstitial Pneumonitis                             | -             | 0.0        | 1             | 0.1        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | 1             | 0.0        |
| 516.33 Acute Interstitial Pneumonitis                                  | 2             | 0.5        | 2             | 0.1        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1                    | 0.5        | 4             | 0.2        |
| 516.34 Bronchiolitis Interstitial Lung Dis                             | 1             | 0.2        | 4             | 0.3        | -            | 0.0        | 1            | 0.8        | -            | 0.0        | -            | 0.0        | 1                    | 0.5        | 6             | 0.2        |
| 516.35 Idiopathic Lymphoid Interstitial Pneumonia                      | -             | 0.0        | -             | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | -             | 0.0        |
| 516.36 Cryptogenic Organizing Pneumonia                                | 1             | 0.2        | 3             | 0.2        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -                    | 0.0        | 4             | 0.2        |
| 516.37 Desquamative Interstitial Pneumonia                             | -             | 0.0        | 1             | 0.1        | -            | 0.0        | -            | 0.0        | -            | 0.0        | -            | 0.0        | 1                    | 0.5        | 1             | 0.0        |
| 516.8 Other Specified Alveolar and Parietoalveolar Pneumonopathies     | 14            | 3.3        | 64            | 4.5        | 10           | 3.4        | 9            | 7.3        | 2            | 4.7        | 2            | 1.6        | 6                    | 2.9        | 101           | 4.2        |
| 516.9 Unspecified Alveolar and Parietoalveolar Pneumonopathy           | 19            | 4.4        | 67            | 4.7        | 8            | 2.7        | 4            | 3.2        | -            | 0.0        | 6            | 4.9        | 1                    | 0.5        | 104           | 4.3        |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

**Table 4. Age / Gender Demographics by Study Drug Cohort for 07/20/2009 - 03/31/2013; US DoD Database**

| Gender / Age Group | Dronedarone   |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide   |             | Propafenone  |            | Total         |            |
|--------------------|---------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|--------------|-------------|--------------|------------|---------------|------------|
|                    | N             | %           | N             | %           | N            | %           | N            | %           | N            | %           | N            | %          | N             | %          |
| <b>Total</b>       | <b>11,626</b> | <b>100</b>  | <b>30,215</b> | <b>100</b>  | <b>8,375</b> | <b>100</b>  | <b>5,285</b> | <b>100</b>  | <b>1,083</b> | <b>100</b>  | <b>3,929</b> | <b>100</b> | <b>60,513</b> | <b>100</b> |
| < 18               | -             | 0.0         | 6             | 0.0         | 4            | 0.0         | 4            | 0.1         | -            | 0.0         | 2            | 0.1        | 16            | 0.0        |
| 18-24              | 6             | 0.1         | 11            | 0.0         | 7            | 0.1         | 46           | 0.9         | 3            | 0.3         | 9            | 0.2        | 82            | 0.1        |
| 25-34              | 34            | 0.3         | 28            | 0.1         | 31           | 0.4         | 147          | 2.8         | 7            | 0.6         | 46           | 1.2        | 293           | 0.5        |
| 35-44              | 118           | 1.0         | 89            | 0.3         | 63           | 0.8         | 225          | 4.3         | 9            | 0.8         | 89           | 2.3        | 593           | 1.0        |
| 45-54              | 474           | 4.1         | 599           | 2.0         | 308          | 3.7         | 460          | 8.7         | 50           | 4.6         | 271          | 6.9        | 2,162         | 3.6        |
| 55-64              | 1,735         | 14.9        | 3,269         | 10.8        | 1,239        | 14.8        | 1,058        | 20.0        | 208          | 19.2        | 702          | 17.9       | 8,211         | 13.6       |
| 65-74              | 4,220         | 36.3        | 9,458         | 31.3        | 2,978        | 35.6        | 1,856        | 35.1        | 439          | 40.5        | 1,401        | 35.7       | 20,352        | 33.6       |
| 75-84              | 3,997         | 34.4        | 12,240        | 40.5        | 2,948        | 35.2        | 1,226        | 23.2        | 317          | 29.3        | 1,118        | 28.5       | 21,846        | 36.1       |
| 85+                | 1,042         | 9.0         | 4,515         | 14.9        | 797          | 9.5         | 263          | 5.0         | 49           | 4.5         | 291          | 7.4        | 6,957         | 11.5       |
| <b>Females</b>     | <b>5,240</b>  | <b>45.1</b> | <b>11,734</b> | <b>38.8</b> | <b>3,781</b> | <b>45.1</b> | <b>2,666</b> | <b>50.4</b> | <b>375</b>   | <b>34.6</b> | <b>1,974</b> | <b>50</b>  | <b>25,770</b> | <b>43</b>  |
| < 18               | -             | 0.0         | 3             | 0.0         | 2            | 0.0         | 1            | 0.0         | -            | 0.0         | 1            | 0.0        | 7             | 0.0        |
| 18-24              | 1             | 0.0         | 1             | 0.0         | 5            | 0.1         | 11           | 0.2         | 3            | 0.3         | 4            | 0.1        | 25            | 0.0        |
| 25-34              | 7             | 0.1         | 7             | 0.0         | 15           | 0.2         | 49           | 0.9         | 3            | 0.3         | 11           | 0.3        | 92            | 0.2        |
| 35-44              | 28            | 0.2         | 20            | 0.1         | 23           | 0.3         | 58           | 1.1         | 1            | 0.1         | 16           | 0.4        | 146           | 0.2        |
| 45-54              | 129           | 1.1         | 151           | 0.5         | 86           | 1.0         | 140          | 2.6         | 13           | 1.2         | 88           | 2.2        | 607           | 1.0        |
| 55-64              | 645           | 5.5         | 893           | 3.0         | 414          | 4.9         | 457          | 8.6         | 54           | 5.0         | 286          | 7.3        | 2,749         | 4.5        |
| 65-74              | 1,826         | 15.7        | 3,264         | 10.8        | 1,260        | 15.0        | 990          | 18.7        | 140          | 12.9        | 716          | 18.2       | 8,196         | 13.5       |
| 75-84              | 1,991         | 17.1        | 5,019         | 16.6        | 1,483        | 17.7        | 770          | 14.6        | 133          | 12.3        | 654          | 16.6       | 10,050        | 16.6       |
| 85+                | 613           | 5.3         | 2,376         | 7.9         | 493          | 5.9         | 190          | 3.6         | 28           | 2.6         | 198          | 5.0        | 3,898         | 6.4        |
| <b>Males</b>       | <b>6,386</b>  | <b>54.9</b> | <b>18,481</b> | <b>61.2</b> | <b>4,594</b> | <b>54.9</b> | <b>2,619</b> | <b>49.6</b> | <b>707</b>   | <b>65.3</b> | <b>1,955</b> | <b>50</b>  | <b>34,742</b> | <b>57</b>  |
| < 18               | -             | 0.0         | 3             | 0.0         | 2            | 0.0         | 3            | 0.1         | -            | 0.0         | 1            | 0.0        | 9             | 0.0        |
| 18-24              | 5             | 0.0         | 10            | 0.0         | 2            | 0.0         | 35           | 0.7         | -            | 0.0         | 5            | 0.1        | 57            | 0.1        |
| 25-34              | 27            | 0.2         | 21            | 0.1         | 16           | 0.2         | 98           | 1.9         | 4            | 0.4         | 35           | 0.9        | 201           | 0.3        |
| 35-44              | 90            | 0.8         | 69            | 0.2         | 40           | 0.5         | 167          | 3.2         | 8            | 0.7         | 73           | 1.9        | 447           | 0.7        |
| 45-54              | 345           | 3.0         | 448           | 1.5         | 222          | 2.7         | 320          | 6.1         | 37           | 3.4         | 183          | 4.7        | 1,555         | 2.6        |
| 55-64              | 1,090         | 9.4         | 2,376         | 7.9         | 825          | 9.9         | 601          | 11.4        | 154          | 14.2        | 416          | 10.6       | 5,462         | 9.0        |
| 65-74              | 2,394         | 20.6        | 6,194         | 20.5        | 1,718        | 20.5        | 866          | 16.4        | 299          | 27.6        | 685          | 17.4       | 12,156        | 20.1       |
| 75-84              | 2,006         | 17.3        | 7,221         | 23.9        | 1,465        | 17.5        | 456          | 8.6         | 184          | 17.0        | 464          | 11.8       | 11,796        | 19.5       |
| 85+                | 429           | 3.7         | 2,139         | 7.1         | 304          | 3.6         | 73           | 1.4         | 21           | 1.9         | 93           | 2.4        | 3,059         | 5.1        |
| <b>Unknown</b>     | <b>-</b>      | <b>0.0</b>  | <b>-</b>      | <b>0.0</b>  | <b>-</b>     | <b>0.0</b>  | <b>-</b>     | <b>0.0</b>  | <b>1</b>     | <b>0.1</b>  | <b>-</b>     | <b>0.0</b> | <b>1</b>      | <b>0.0</b> |

**Figure 1. Age Demographics of Study Drug Cohorts;  
US DoD Database: July 20, 2009 - March 31, 2013**

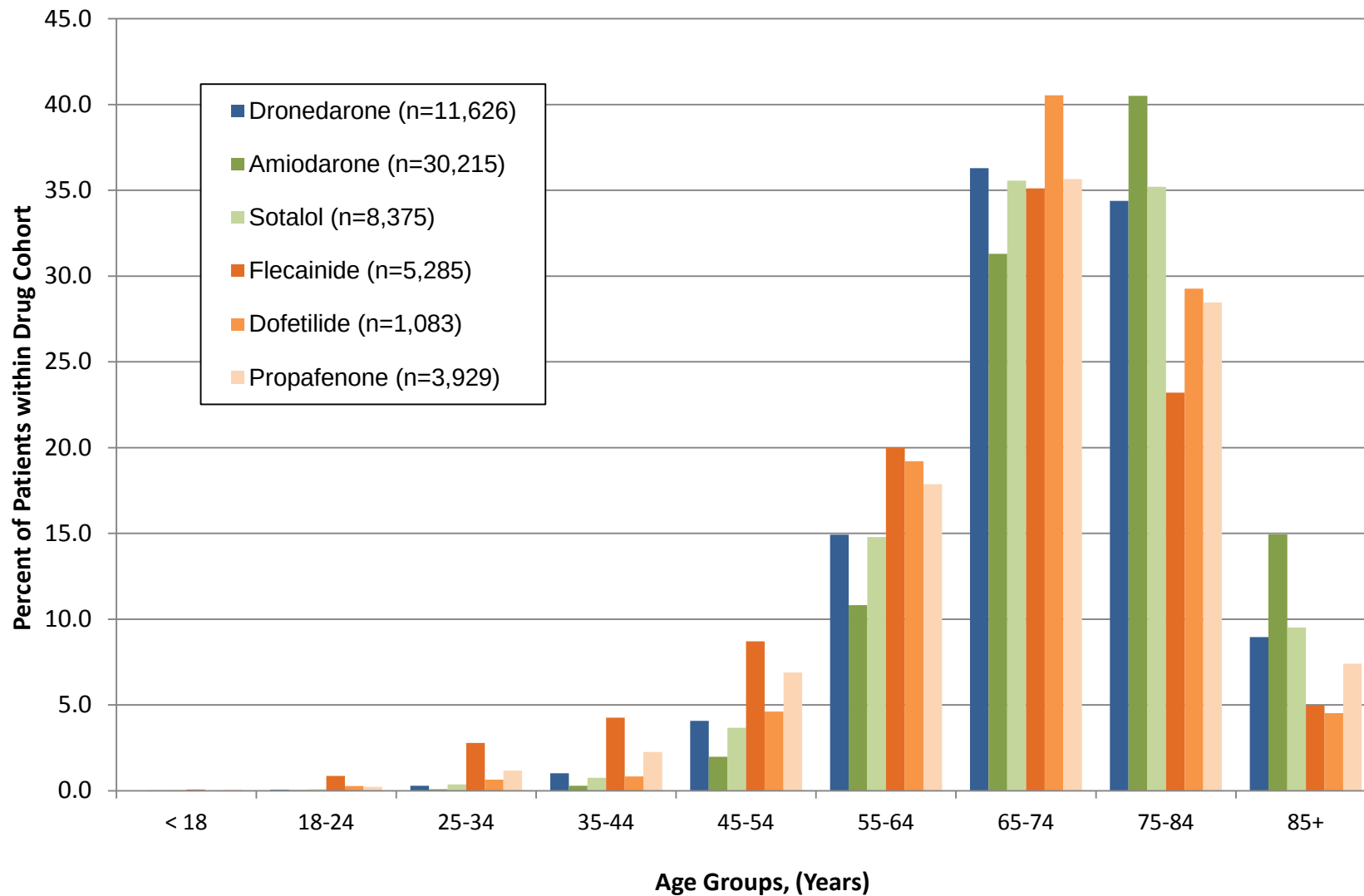




**Table 1. Number of Patients with a Study Drug of Interest between 7/20/2009 and 06/30/2013, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Screening Description                                             | Dronedarone   |            | Amiodarone    |            | Sotalol       |            | Flecainide    |            | Dofetilide   |            | Propafenone   |            | Total          |            |
|-------------------------------------------------------------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|--------------|------------|---------------|------------|----------------|------------|
|                                                                   | N             | %          | N             | %          | N             | %          | N             | %          | N            | %          | N             | %          | N              | %          |
| <b>Assign the first study drug as the cohort</b>                  | <b>14,349</b> | <b>100</b> | <b>64,344</b> | <b>100</b> | <b>24,750</b> | <b>100</b> | <b>14,259</b> | <b>100</b> | <b>2,834</b> | <b>100</b> | <b>10,942</b> | <b>100</b> | <b>131,978</b> | <b>100</b> |
| Less patients without 365 days of eligibility prior to index date | 201           | 1%         | 648           | 1%         | 608           | 2%         | 547           | 4%         | 74           | 3%         | 265           | 2%         | 2,343          | 2%         |
| Less patients without AF in the year prior to index date          | 2,069         | 14%        | 17,380        | 27%        | 5,844         | 24%        | 3,977         | 28%        | 302          | 11%        | 2,495         | 23%        | 32,068         | 24%        |
| Less patients with the index drug in the year prior to index date | 0             | 0%         | 13,989        | 22%        | 9,384         | 38%        | 4,025         | 28%        | 1,306        | 46%        | 4,045         | 37%        | 32,750         | 25%        |
| Less patients with multiple study drugs on index date             | 2             | 0%         | 26            | 0%         | 0             | 0%         | 3             | 0%         | 0            | 0%         | 3             | 0%         | 34             | 0.0%       |
| Less patients with date of death preceding index date             | 3             | 0%         | 9             | 0%         | 4             | 0%         | 2             | 0%         | 0            | 0%         | 1             | 0%         | 19             | 0.0%       |
| Less patients below 18 years old on index date*                   | 0             | 0%         | 7             | 0%         | 4             | 0%         | 4             | 0%         | 0            | 0%         | 2             | 0%         | 17             | 0.0%       |
| Less patients with cancer or organ transplant in baseline period* | 2,042         | 14%        | 6,991         | 11%        | 1,555         | 6%         | 696           | 5%         | 173          | 6%         | 639           | 6%         | 12,096         | 9%         |
| Less patients with HIV in baseline period*                        | 2             | 0%         | 9             | 0%         | 2             | 0%         | 4             | 0%         | 1            | 0%         | 2             | 0%         | 20             | 0.0%       |
| Less patients with pregnancy codes prior and/or post index date*  | 8             | 0%         | 27            | 0%         | 13            | 0%         | 16            | 0%         | 2            | 0%         | 6             | 0%         | 72             | 0.1%       |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>10,022</b> | <b>70%</b> | <b>25,258</b> | <b>39%</b> | <b>7,336</b>  | <b>30%</b> | <b>4,985</b>  | <b>35%</b> | <b>976</b>   | <b>34%</b> | <b>3,484</b>  | <b>32%</b> | <b>52,063</b>  | <b>39%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Serious Liver Injury/Disease (SLD) - Prior SLD Screening*</b> | Dronedarone  |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|--------------|------------|---------------|------------|--------------|------------|--------------|------------|------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,022       | 70%        | 25,258        | 39%        | 7,336        | 30%        | 4,985        | 35%        | 976        | 34%        | 3,484        | 32%        | 52,063        | 39%        |
| Less patients with SLD in baseline period                        | 419          | 3%         | 1,490         | 2%         | 385          | 2%         | 195          | 1%         | 52         | 2%         | 138          | 1%         | 2,679         | 2%         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                    | <b>9,603</b> | <b>67%</b> | <b>23,768</b> | <b>37%</b> | <b>6,951</b> | <b>28%</b> | <b>4,790</b> | <b>34%</b> | <b>924</b> | <b>33%</b> | <b>3,346</b> | <b>31%</b> | <b>49,384</b> | <b>37%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Interstitial Lung Disease (ILD) - Prior ILD Screening*</b>    | Dronedarone  |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|--------------|------------|---------------|------------|--------------|------------|--------------|------------|------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,022       | 70%        | 25,258        | 39%        | 7,336        | 30%        | 4,985        | 35%        | 976        | 34%        | 3,484        | 32%        | 52,063        | 39%        |
| Less patients with ILD in baseline period                        | 544          | 4%         | 2,329         | 4%         | 448          | 2%         | 157          | 1%         | 66         | 2%         | 170          | 2%         | 3,714         | 3%         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                    | <b>9,478</b> | <b>66%</b> | <b>22,929</b> | <b>36%</b> | <b>6,888</b> | <b>28%</b> | <b>4,828</b> | <b>34%</b> | <b>910</b> | <b>32%</b> | <b>3,314</b> | <b>30%</b> | <b>48,349</b> | <b>37%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

**Table 2. Number of Patients with at least One Serious Liver Injury/Disease Definition Code Post Index Date by Study Cohort between 07/20/2009 - 6/30/2013; US DoD Database**

| Surveillance from 7/20/2009 - 6/30/2013                              | Dronedarone  |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide |            | Propafenone  |            | Total         |            |
|----------------------------------------------------------------------|--------------|------------|---------------|------------|--------------|------------|--------------|------------|------------|------------|--------------|------------|---------------|------------|
|                                                                      | N            | %          | N             | %          | N            | %          | N            | %          | N          | %          | N            | %          | N             | %          |
| <b>Total Patients After Screening for Prior SLD</b>                  | <b>9,603</b> | <b>100</b> | <b>23,768</b> | <b>100</b> | <b>6,951</b> | <b>100</b> | <b>4,790</b> | <b>100</b> | <b>924</b> | <b>100</b> | <b>3,346</b> | <b>100</b> | <b>49,382</b> | <b>100</b> |
| <b>Patients with at least 1 occurrence of an SLD definition code</b> | <b>523</b>   | <b>5.4</b> | <b>1,444</b>  | <b>6.1</b> | <b>323</b>   | <b>4.6</b> | <b>179</b>   | <b>3.7</b> | <b>42</b>  | <b>4.5</b> | <b>165</b>   | <b>4.9</b> | <b>2,676</b>  | <b>5.4</b> |
| <b>ICD-9-CM Diagnosis*</b>                                           |              |            |               |            |              |            |              |            |            |            |              |            |               |            |
| <b>277.4 Disorders of Bilirubin Excretion</b>                        | <b>14</b>    | <b>2.7</b> | <b>35</b>     | <b>2.4</b> | <b>15</b>    | <b>4.6</b> | <b>4</b>     | <b>2.2</b> | <b>1</b>   | <b>2.4</b> | <b>1</b>     | <b>0.6</b> | <b>70</b>     | <b>2.6</b> |
| 570 Acute and Subacute Necrosis of Liver                             | 28           | 5.4        | 133           | 9.2        | 14           | 4.3        | 10           | 5.6        | 2          | 4.8        | 0            | 0.0        | 187           | 7.0        |
| 571.5 Cirrhosis Of Liver without Mention of Alcohol                  | 34           | 6.5        | 92            | 6.4        | 13           | 4.0        | 3            | 1.7        | 4          | 9.5        | 9            | 5.5        | 155           | 5.8        |
| 572.2 Hepatic Coma                                                   | 8            | 1.5        | 31            | 2.1        | 2            | 0.6        | 0            | 0.0        | 1          | 2.4        | 3            | 1.8        | 45            | 1.7        |
| 572.4 Hepatorenal Syndrome                                           | 2            | 0.4        | 10            | 0.7        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 12            | 0.4        |
| <b>572.8 Other Sequelae of Chronic Liver Disease</b>                 | <b>7</b>     | <b>1.3</b> | <b>26</b>     | <b>1.8</b> | <b>4</b>     | <b>1.2</b> | <b>1</b>     | <b>0.6</b> | <b>1</b>   | <b>2.4</b> | <b>3</b>     | <b>1.8</b> | <b>42</b>     | <b>1.6</b> |
| 573.0 Chronic Passive Congestion Of Liver                            | 3            | 0.6        | 28            | 1.9        | 4            | 1.2        | 2            | 1.1        | 0          | 0.0        | 2            | 1.2        | 39            | 1.5        |
| 573.3 Hepatitis, Unspecified                                         | 34           | 6.5        | 113           | 7.8        | 22           | 6.8        | 9            | 5.0        | 3          | 7.1        | 15           | 9.1        | 196           | 7.3        |
| 573.8 Other Specified Disorders of Liver                             | 190          | 36.3       | 389           | 26.9       | 130          | 40.2       | 66           | 36.9       | 14         | 33.3       | 53           | 32.1       | 842           | 31.5       |
| 573.9 Unspecified Disorder of the Liver                              | 38           | 7.3        | 122           | 8.4        | 24           | 7.4        | 12           | 6.7        | 5          | 11.9       | 23           | 13.9       | 224           | 8.4        |
| 782.4 Jaundice, Unspecified                                          | 38           | 7.3        | 110           | 7.6        | 25           | 7.7        | 9            | 5.0        | 1          | 2.4        | 12           | 7.3        | 195           | 7.3        |
| 794.8 Nonspecific Abnormal Results of Liver Function Test            | 141          | 27.0       | 399           | 27.6       | 88           | 27.2       | 64           | 35.8       | 11         | 26.2       | 44           | 26.7       | 747           | 27.9       |
| V42.7 Liver replaced by Transplant                                   | 1            | 0.2        | 1             | 0.1        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 2             | 0.1        |
| <b>ICD-9-CM Procedures*</b>                                          |              |            |               |            |              |            |              |            |            |            |              |            |               |            |
| 50.11 Closed (Percutaneous) [needle] Biopsy of Liver                 | 6            | 1.1        | 15            | 1.0        | 3            | 0.9        | 2            | 1.1        | 0          | 0.0        | 1            | 0.6        | 27            | 1.0        |
| 50.12 Open Biopsy of Liver                                           | 1            | 0.2        | 1             | 0.1        | 1            | 0.3        | 0            | 0.0        | 0          | 0.0        | 1            | 0.6        | 4             | 0.1        |
| 50.13 Transjugular Liver Biopsy                                      | 0            | 0.0        | 3             | 0.2        | 1            | 0.3        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 4             | 0.1        |
| 50.14 Laparoscopic Liver Biopsy                                      | 4            | 0.8        | 1             | 0.1        | 0            | 0.0        | 1            | 0.6        | 1          | 2.4        | 1            | 0.6        | 8             | 0.3        |
| 50.5 Liver transplant                                                | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |
| 50.51 Auxiliary Liver Transplant                                     | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |
| 50.59 Other Transplant of Liver                                      | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |
| 50.91 Percutaneous Aspiration of Liver                               | 0            | 0.0        | 4             | 0.3        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 1            | 0.6        | 5             | 0.2        |
| <b>CPT* Procedures*</b>                                              |              |            |               |            |              |            |              |            |            |            |              |            |               |            |
| 47000 Biopsy of Liver, Needle: Percutaneous                          | 5            | 1.0        | 18            | 1.2        | 4            | 1.2        | 3            | 1.7        | 0          | 0.0        | 1            | 0.6        | 31            | 1.2        |
| 47001 Biopsy of Liver, Needle: Done At Time Or Other                 | 3            | 0.6        | 2             | 0.1        | 2            | 0.6        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 7             | 0.3        |
| 47100 Biopsy of Liver, wedge                                         | 2            | 0.4        | 5             | 0.3        | 1            | 0.3        | 1            | 0.6        | 1          | 2.4        | 0            | 0.0        | 10            | 0.4        |
| 47135 Liver allotransplantation, orthotopic                          | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |
| 47136 Liver Allotransplantation, heterotopi                          | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |
| 78205 Liver Imaging (Spect)                                          | 0            | 0.0        | 1             | 0.1        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 1             | 0.0        |
| 78206 Liver Imaging (Spect), with vascular flow                      | 0            | 0.0        | 0             | 0.0        | 0            | 0.0        | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        | 0             | 0.0        |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

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Note: Patient counts reflect the only the first occurrence after the index date of a diagnosis/procedure code that defines SLD.



**Table 3. Number of Patients with at least One Interstitial Lung Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 - 6/30/2013; US DoD Database**

| Surveillance from 7/20/2009 - 6/30/2013                            | Dronedarone |      | Amiodarone |      | Sotalol |      | Flecainide |      | Dofetilide |      | Propafenone |      | Total  |      |
|--------------------------------------------------------------------|-------------|------|------------|------|---------|------|------------|------|------------|------|-------------|------|--------|------|
|                                                                    | N           | %    | N          | %    | N       | %    | N          | %    | N          | %    | N           | %    | N      | %    |
| Total Patients After Screening for Prior ILD                       | 9,478       | 100  | 22,929     | 100  | 6,888   | 100  | 4,828      | 100  | 910        | 100  | 3,314       | 100  | 48,347 | 100  |
| Patients with at least 1 occurrence of an ILD definition code      | 465         | 4.9  | 1,618      | 7.1  | 336     | 4.9  | 146        | 3.0  | 50         | 5.5  | 129         | 3.9  | 2,744  | 5.7  |
| ICD-9-CM Diagnosis*                                                |             |      |            |      |         |      |            |      |            |      |             |      |        |      |
| 495.9 Unspecified Allergic Alveolitis and Pneumonitis              | 6           | 1.3  | 16         | 1.0  | 3       | 0.9  | 1          | 0.7  | 1          | 2.0  | 3           | 2.3  | 30     | 1.1  |
| 515 Postinflammatory Pulmonary Fibrosis                            | 269         | 57.8 | 890        | 55.0 | 208     | 61.9 | 94         | 64.4 | 33         | 66.0 | 88          | 68.2 | 1,582  | 57.7 |
| 516.3 Idiopathic Fibrosing Alveolitis                              | 11          | 2.4  | 31         | 1.9  | 7       | 2.1  | 2          | 1.4  | 0          | 0.0  | 2           | 1.6  | 53     | 1.9  |
| 516.30 Idiopathic Interstitial Pneumonia Unspec                    | 3           | 0.6  | 9          | 0.6  | 3       | 0.9  | 0          | 0.0  | 0          | 0.0  | 1           | 0.8  | 16     | 0.6  |
| 516.31 Idiopathic Pulmonary Fibrosis                               | 5           | 1.1  | 24         | 1.5  | 5       | 1.5  | 1          | 0.7  | 0          | 0.0  | 3           | 2.3  | 38     | 1.4  |
| 516.32 Idiopathic Interstitial Pneumonitis                         | 0           | 0.0  | 2          | 0.1  | 0       | 0.0  | 0          | 0.0  | 0          | 0.0  | 0           | 0.0  | 2      | 0.1  |
| 516.33 Acute Interstitial Pneumonitis                              | 2           | 0.4  | 1          | 0.1  | 0       | 0.0  | 0          | 0.0  | 0          | 0.0  | 0           | 0.0  | 3      | 0.1  |
| 516.34 Bronchiolitis Interstitial Lung Dis                         | 0           | 0.0  | 4          | 0.2  | 0       | 0.0  | 1          | 0.7  | 0          | 0.0  | 0           | 0.0  | 5      | 0.2  |
| 516.35 Idiopathic Lymphoid Interstitial Pneumonia                  | 0           | 0.0  | 0          | 0.0  | 0       | 0.0  | 0          | 0.0  | 0          | 0.0  | 0           | 0.0  | 0      | 0.0  |
| 516.36 Cryptogenic Organizing Pneumonia                            | 0           | 0.0  | 2          | 0.1  | 0       | 0.0  | 0          | 0.0  | 0          | 0.0  | 0           | 0.0  | 2      | 0.1  |
| 516.37 Desquamative Interstitial Pneumonia                         | 0           | 0.0  | 1          | 0.1  | 0       | 0.0  | 0          | 0.0  | 0          | 0.0  | 0           | 0.0  | 1      | 0.0  |
| 516.8 Other Specified Alveolar and Parietoalveolar Pneumonopathies | 13          | 2.8  | 43         | 2.7  | 7       | 2.1  | 6          | 4.1  | 1          | 2.0  | 2           | 1.6  | 72     | 2.6  |
| 516.9 Unspecified Alveolar and Parietoalveolar Pneumonopathy       | 12          | 2.6  | 43         | 2.7  | 6       | 1.8  | 3          | 2.1  | 0          | 0.0  | 3           | 2.3  | 67     | 2.4  |
| 518.82 Acute Respiratory Distress Syndrome                         | 152         | 32.7 | 578        | 35.7 | 101     | 30.1 | 41         | 28.1 | 16         | 32.0 | 30          | 23.3 | 918    | 33.5 |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome. Blue text indicates an additional code added.

Note: Patient counts reflect the only the first occurrence after the index date of a diagnosis code that defines ILD.

**Table 4. Age / Gender Demographics by Study Drug Cohort for 7/20/2009 - 6/30/2013; US DoD Database**

| Gender / Age Groups   | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide |              | Propafenone  |              | Total         |              |
|-----------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|------------|--------------|--------------|--------------|---------------|--------------|
|                       | N             | %            | N             | %            | N            | %            | N            | %            | N          | %            | N            | %            | N             | %            |
| <b>Total</b>          | <b>10,022</b> | <b>100.0</b> | <b>25,258</b> | <b>100.0</b> | <b>7,336</b> | <b>100.0</b> | <b>4,985</b> | <b>100.0</b> | <b>976</b> | <b>100.0</b> | <b>3,484</b> | <b>100.0</b> | <b>52,061</b> | <b>100.0</b> |
| 18-24                 | 8             | 0.1          | 11            | 0.0          | 6            | 0.1          | 43           | 0.9          | 2          | 0.2          | 9            | 0.3          | 79            | 0.2          |
| 25-34                 | 35            | 0.3          | 27            | 0.1          | 27           | 0.4          | 142          | 2.8          | 6          | 0.6          | 45           | 1.3          | 282           | 0.5          |
| 35-44                 | 115           | 1.1          | 87            | 0.3          | 62           | 0.8          | 237          | 4.8          | 11         | 1.1          | 84           | 2.4          | 596           | 1.1          |
| 45-54                 | 468           | 4.7          | 561           | 2.2          | 292          | 4.0          | 466          | 9.3          | 50         | 5.1          | 273          | 7.8          | 2,110         | 4.1          |
| 55-64                 | 1,613         | 16.1         | 2,888         | 11.4         | 1,166        | 15.9         | 1,057        | 21.2         | 205        | 21.0         | 661          | 19.0         | 7,590         | 14.6         |
| 65-74                 | 3,641         | 36.3         | 7,924         | 31.4         | 2,648        | 36.1         | 1,725        | 34.6         | 387        | 39.7         | 1,247        | 35.8         | 17,572        | 33.8         |
| 75-84                 | 3,280         | 32.7         | 9,983         | 39.5         | 2,469        | 33.7         | 1,081        | 21.7         | 277        | 28.4         | 920          | 26.4         | 18,010        | 34.6         |
| 85+                   | 862           | 8.6          | 3,777         | 15.0         | 666          | 9.1          | 234          | 4.7          | 38         | 3.9          | 245          | 7.0          | 5,822         | 11.2         |
| <b>Female</b>         | <b>4,616</b>  | <b>46.1</b>  | <b>10,151</b> | <b>40.2</b>  | <b>3,390</b> | <b>46.2</b>  | <b>2,526</b> | <b>50.7</b>  | <b>340</b> | <b>34.8</b>  | <b>1,796</b> | <b>51.5</b>  | <b>22,819</b> | <b>43.8</b>  |
| 18-24                 | 1             | 0.0          | 1             | 0.0          | 4            | 0.1          | 8            | 0.2          | 2          | 0.2          | 4            | 0.1          | 20            | 0.0          |
| 25-34                 | 7             | 0.1          | 4             | 0.0          | 10           | 0.1          | 43           | 0.9          | 2          | 0.2          | 10           | 0.3          | 76            | 0.1          |
| 35-44                 | 24            | 0.2          | 22            | 0.1          | 20           | 0.3          | 63           | 1.3          | 3          | 0.3          | 13           | 0.4          | 145           | 0.3          |
| 45-54                 | 123           | 1.2          | 133           | 0.5          | 80           | 1.1          | 142          | 2.8          | 11         | 1.1          | 86           | 2.5          | 575           | 1.1          |
| 55-64                 | 587           | 5.9          | 766           | 3.0          | 384          | 5.2          | 454          | 9.1          | 51         | 5.2          | 271          | 7.8          | 2,513         | 4.8          |
| 65-74                 | 1,587         | 15.8         | 2,765         | 10.9         | 1,143        | 15.6         | 925          | 18.6         | 125        | 12.8         | 650          | 18.7         | 7,195         | 13.8         |
| 75-84                 | 1,741         | 17.4         | 4,314         | 17.1         | 1,308        | 17.8         | 718          | 14.4         | 125        | 12.8         | 583          | 16.7         | 8,789         | 16.9         |
| 85+                   | 546           | 5.4          | 2,146         | 8.5          | 441          | 6.0          | 173          | 3.5          | 21         | 2.2          | 179          | 5.1          | 3,506         | 6.7          |
| <b>Male</b>           | <b>5,406</b>  | <b>53.9</b>  | <b>15,107</b> | <b>59.8</b>  | <b>3,946</b> | <b>53.8</b>  | <b>2,459</b> | <b>49.3</b>  | <b>635</b> | <b>65.1</b>  | <b>1,688</b> | <b>48.5</b>  | <b>29,241</b> | <b>56.2</b>  |
| 18-24                 | 7             | 0.1          | 10            | 0.0          | 2            | 0.0          | 35           | 0.7          | 0          | 0.0          | 5            | 0.1          | 59            | 0.1          |
| 25-34                 | 28            | 0.3          | 23            | 0.1          | 17           | 0.2          | 99           | 2.0          | 4          | 0.4          | 35           | 1.0          | 206           | 0.4          |
| 35-44                 | 91            | 0.9          | 65            | 0.3          | 42           | 0.6          | 174          | 3.5          | 8          | 0.8          | 71           | 2.0          | 451           | 0.9          |
| 45-54                 | 345           | 3.4          | 428           | 1.7          | 212          | 2.9          | 324          | 6.5          | 39         | 4.0          | 187          | 5.4          | 1,535         | 2.9          |
| 55-64                 | 1,026         | 10.2         | 2,122         | 8.4          | 782          | 10.7         | 603          | 12.1         | 154        | 15.8         | 390          | 11.2         | 5,077         | 9.8          |
| 65-74                 | 2,054         | 20.5         | 5,159         | 20.4         | 1,505        | 20.5         | 800          | 16.0         | 261        | 26.7         | 597          | 17.1         | 10,376        | 19.9         |
| 75-84                 | 1,539         | 15.4         | 5,669         | 22.4         | 1,161        | 15.8         | 363          | 7.3          | 152        | 15.6         | 337          | 9.7          | 9,221         | 17.7         |
| 85+                   | 316           | 3.2          | 1,631         | 6.5          | 225          | 3.1          | 61           | 1.2          | 17         | 1.7          | 66           | 1.9          | 2,316         | 4.4          |
| <b>Unknown Gender</b> | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>   | <b>0.1</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>      | <b>0.0</b>   |
| 65-74                 | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 1          | 0.1          | 0            | 0.0          | 1             | 0.0          |

**Figure 1. Age Demographics of Study Drug Cohorts;  
US DoD Database: July 20, 2009 - June 30, 2013**

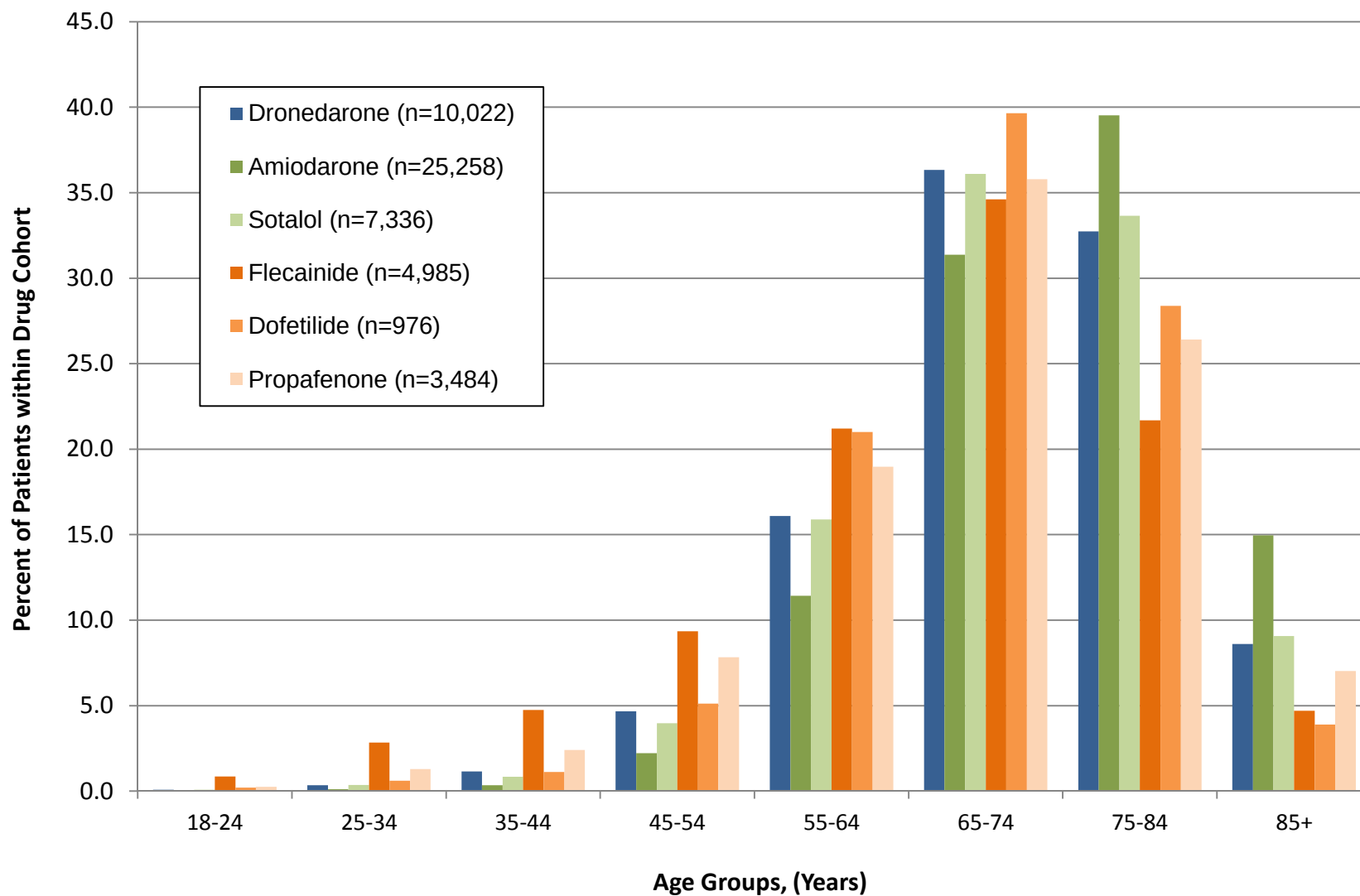




**Table 1. Number of Patients with a Study Drug of Interest between 7/20/2009 and 03/31/2014, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Screening Description                                             | Dronedarone   |            | Amiodarone    |            | Sotalol       |            | Flecainide    |            | Dofetilide   |            | Propafenone   |            | Total          |            |
|-------------------------------------------------------------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|--------------|------------|---------------|------------|----------------|------------|
|                                                                   | N             | %          | N             | %          | N             | %          | N             | %          | N            | %          | N             | %          | N              | %          |
| <b>Assign the first study drug as the cohort</b>                  | <b>15,890</b> | <b>100</b> | <b>72,574</b> | <b>100</b> | <b>26,818</b> | <b>100</b> | <b>16,115</b> | <b>100</b> | <b>3,093</b> | <b>100</b> | <b>11,789</b> | <b>100</b> | <b>146,279</b> | <b>100</b> |
| Less patients without 365 days of eligibility prior to index date | 233           | 1%         | 751           | 1%         | 732           | 3%         | 653           | 4%         | 90           | 3%         | 302           | 3%         | 2,761          | 2%         |
| Less patients without AF in the year prior to index date          | 2,564         | 16%        | 20,548        | 28%        | 6,645         | 25%        | 4,721         | 29%        | 343          | 11%        | 2,826         | 24%        | 37,647         | 26%        |
| Less patients with the index drug in the year prior to index date | 0             | 0%         | 13,847        | 19%        | 9,274         | 35%        | 3,977         | 25%        | 1,300        | 42%        | 4,013         | 34%        | 32,411         | 22%        |
| Less patients with multiple study drugs on index date             | 2             | 0%         | 28            | 0%         | 0             | 0%         | 2             | 0%         | 0            | 0%         | 3             | 0%         | 35             | 0%         |
| Less patients with date of death preceding index date             | 4             | 0%         | 10            | 0%         | 4             | 0%         | 2             | 0%         | 0            | 0%         | 1             | 0%         | 21             | 0%         |
| Less patients below 18 years old on index date*                   | 0             | 0%         | 4             | 0%         | 2             | 0%         | 3             | 0%         | 0            | 0%         | 2             | 0%         | 11             | 0%         |
| Less patients with cancer or organ transplant in baseline period* | 2,197         | 14%        | 7,996         | 11%        | 1,764         | 7%         | 826           | 5%         | 204          | 7%         | 725           | 6%         | 13,712         | 9%         |
| Less patients with HIV in baseline period*                        | 2             | 0.0        | 12            | 0.0        | 2             | 0.0        | 5             | 0.0        | 1            | 0.0        | 2             | 0.0        | 24             | 0.0        |
| Less patients with pregnancy codes prior and/or post index date*  | 8             | 0%         | 34            | 0%         | 14            | 0%         | 20            | 0%         | 2            | 0%         | 7             | 0%         | 85             | 0%         |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>10,880</b> | <b>68%</b> | <b>29,344</b> | <b>40%</b> | <b>8,381</b>  | <b>31%</b> | <b>5,906</b>  | <b>37%</b> | <b>1,153</b> | <b>37%</b> | <b>3,908</b>  | <b>33%</b> | <b>59,572</b>  | <b>41%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Serious Liver Injury/Disease (SLD) - Prior SLD Screening*</b> | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,344        | 40%        | 8,381        | 31%        | 5,906        | 37%        | 1,153        | 37%        | 3,908        | 33%        | 59,572        | 41%        |
| Less patients with SLD in baseline period                        | 460           | 3%         | 1,742         | 2%         | 444          | 2%         | 230          | 1%         | 68           | 2%         | 144          | 1%         | 3,088         | 2%         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                    | <b>10,420</b> | <b>66%</b> | <b>27,602</b> | <b>38%</b> | <b>7,937</b> | <b>30%</b> | <b>5,676</b> | <b>35%</b> | <b>1,085</b> | <b>35%</b> | <b>3,764</b> | <b>32%</b> | <b>56,484</b> | <b>39%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Interstitial Lung Disease (ILD) - Prior ILD Screening*</b>    | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,344        | 40%        | 8,381        | 31%        | 5,906        | 37%        | 1,153        | 37%        | 3,908        | 33%        | 59,572        | 41%        |
| Less patients with ILD in baseline period                        | 584           | 4%         | 2,654         | 4%         | 505          | 2%         | 173          | 1.1        | 84           | 2.7        | 187          | 1.6        | 4,187         | 3%         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                    | <b>10,296</b> | <b>65%</b> | <b>26,690</b> | <b>37%</b> | <b>7,876</b> | <b>29%</b> | <b>5,733</b> | <b>36%</b> | <b>1,069</b> | <b>35%</b> | <b>3,721</b> | <b>32%</b> | <b>55,385</b> | <b>38%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

**Table 2. Number of Patients with at least One Serious Liver Injury/Disease Definition Code Post Index Date by Study Cohort between 07/20/2009 - 3/31/2014; US DoD Database**

| Surveillance from 7/20/2009 to 3/31/2014                       | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|----------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                                                                | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total Patients</b>                                          | <b>10,420</b> | <b>100.0</b> | <b>27,602</b> | <b>100.0</b> | <b>7,937</b> | <b>100.0</b> | <b>5,676</b> | <b>100.0</b> | <b>1,085</b> | <b>100.0</b> | <b>3,764</b> | <b>100.0</b> | <b>56,484</b> | <b>100.0</b> |
| <b>Patients with ≥ 1 occurrence of an SLD code</b>             | <b>604</b>    | <b>5.8</b>   | <b>1,756</b>  | <b>6.4</b>   | <b>411</b>   | <b>5.2</b>   | <b>249</b>   | <b>4.4</b>   | <b>58</b>    | <b>5.3</b>   | <b>200</b>   | <b>5.3</b>   | <b>3,278</b>  | <b>5.8</b>   |
| <b>ICD-9-CM Diagnosis</b>                                      |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 277.4 Disorders of bilirubin excretion                         | 17            | 0.2          | 47            | 0.2          | 17           | 0.2          | 6            | 0.1          | 2            | 0.2          | 3            | 0.1          | 92            | 0.2          |
| 570 Acute and subacute necrosis of liver                       | 32            | 0.3          | 163           | 0.6          | 21           | 0.3          | 14           | 0.2          | 3            | 0.3          | 1            | 0.0          | 234           | 0.4          |
| 571.5 Cirrhosis of liver without mention of alcohol            | 39            | 0.4          | 117           | 0.4          | 23           | 0.3          | 10           | 0.2          | 6            | 0.6          | 14           | 0.4          | 209           | 0.4          |
| 572.2 Hepatic coma                                             | 8             | 0.1          | 37            | 0.1          | 2            | 0.0          | 0            | 0.0          | 1            | 0.1          | 4            | 0.1          | 52            | 0.1          |
| 572.4 Hepatorenal syndrome                                     | 3             | 0.0          | 11            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 14            | 0.0          |
| 572.8 Other sequelae of chronic liver disease                  | 7             | 0.1          | 30            | 0.1          | 5            | 0.1          | 2            | 0.0          | 1            | 0.1          | 2            | 0.1          | 47            | 0.1          |
| 573.0 Chronic passive congestion of liver                      | 3             | 0.0          | 38            | 0.1          | 6            | 0.1          | 2            | 0.0          | 0            | 0.0          | 2            | 0.1          | 51            | 0.1          |
| 573.3 Hepatitis, unspecified                                   | 37            | 0.4          | 129           | 0.5          | 29           | 0.4          | 12           | 0.2          | 4            | 0.4          | 17           | 0.5          | 228           | 0.4          |
| 573.8 Other specified disorders of liver                       | 224           | 2.1          | 483           | 1.7          | 162          | 2.0          | 97           | 1.7          | 18           | 1.7          | 66           | 1.8          | 1,050         | 1.9          |
| 573.9 Unspecified disorder of the liver                        | 46            | 0.4          | 153           | 0.6          | 31           | 0.4          | 22           | 0.4          | 7            | 0.6          | 29           | 0.8          | 288           | 0.5          |
| 782.4 Jaundice, unspecified                                    | 44            | 0.4          | 141           | 0.5          | 30           | 0.4          | 12           | 0.2          | 4            | 0.4          | 13           | 0.3          | 244           | 0.4          |
| 794.8 Nonspecific abnormal results of liver function test      | 159           | 1.5          | 471           | 1.7          | 104          | 1.3          | 77           | 1.4          | 14           | 1.3          | 48           | 1.3          | 873           | 1.5          |
| V42.7 Liver replaced by transplant                             | 1             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 5             | 0.0          |
| <b>ICD-9-CM Procedures</b>                                     |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver           | 6             | 0.1          | 21            | 0.1          | 3            | 0.0          | 2            | 0.0          | 0            | 0.0          | 1            | 0.0          | 33            | 0.1          |
| 50.12 Open biopsy of liver                                     | 1             | 0.0          | 1             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 4             | 0.0          |
| 50.13 Transjugular liver biopsy                                | 0             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 4             | 0.0          |
| 50.14 Laparoscopic liver biopsy                                | 5             | 0.0          | 1             | 0.0          | 0            | 0.0          | 1            | 0.0          | 1            | 0.1          | 1            | 0.0          | 9             | 0.0          |
| 50.5 Liver transplant                                          | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.51 Auxiliary liver transplant                               | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.59 Other transplant of liver                                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.91 Percutaneous aspiration of liver                         | 0             | 0.0          | 3             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 4             | 0.0          |
| <b>CPT® Procedures</b>                                         |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 47000 Biopsy of liver, needle: percutaneous                    | 7             | 0.1          | 20            | 0.1          | 5            | 0.1          | 4            | 0.1          | 0            | 0.0          | 2            | 0.1          | 38            | 0.1          |
| 47001 Biopsy of liver, needle: done at time or other           | 3             | 0.0          | 4             | 0.0          | 2            | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 10            | 0.0          |
| 47100 Biopsy of liver, wedge                                   | 2             | 0.0          | 5             | 0.0          | 1            | 0.0          | 1            | 0.0          | 1            | 0.1          | 0            | 0.0          | 10            | 0.0          |
| 47135 Liver allotransplantation, orthotopic, partial or whole  | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 47136 Liver allotransplantation, heterotopic, partial or whole | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 78205 Liver imaging (Spect)                                    | 0             | 0.0          | 1             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1             | 0.0          |
| 78206 Liver imaging (Spect), with vascular flow                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

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Note: Patient counts reflect the only the first occurrence after the index date of a diagnosis/procedure code that defines SLD.

**Table 3. Number of Patients with at least One Interstitial Lung Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 - 3/31/2014; US DoD Database**

| Surveillance from 7/20/2009 to 3/31/2014                           | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|--------------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                                                                    | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total patients</b>                                              | <b>10,296</b> | <b>100.0</b> | <b>26,690</b> | <b>100.0</b> | <b>7,876</b> | <b>100.0</b> | <b>5,733</b> | <b>100.0</b> | <b>1,069</b> | <b>100.0</b> | <b>3,721</b> | <b>100.0</b> | <b>55,385</b> | <b>100.0</b> |
| <b>Patients with <math>\geq 1</math> occurrence of an ILD code</b> | <b>551</b>    | <b>5.4</b>   | <b>1,946</b>  | <b>7.3</b>   | <b>424</b>   | <b>5.4</b>   | <b>176</b>   | <b>3.1</b>   | <b>62</b>    | <b>5.8</b>   | <b>154</b>   | <b>4.1</b>   | <b>3,313</b>  | <b>6.0</b>   |
| <b>ICD-9-CM Diagnosis*</b>                                         |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 495.9 Unspecified allergic alveolitis and pneumonitis              | 6             | 0.1          | 18            | 0.1          | 3            | 0.0          | 1            | 0.0          | 1            | 0.1          | 3            | 0.1          | 32            | 0.1          |
| 515 Postinflammatory pulmonary fibrosis                            | 330           | 3.2          | 1,088         | 4.1          | 261          | 3.3          | 114          | 2.0          | 38           | 3.6          | 99           | 2.7          | 1,930         | 3.5          |
| 516.3 Idiopathic fibrosing alveolitis                              | 11            | 0.1          | 30            | 0.1          | 7            | 0.1          | 2            | 0.0          | 0            | 0.0          | 2            | 0.1          | 52            | 0.1          |
| 516.30 Idiopathic interstitial pneumonia unspec                    | 4             | 0.0          | 13            | 0.0          | 4            | 0.1          | 1            | 0.0          | 0            | 0.0          | 2            | 0.1          | 24            | 0.0          |
| 516.31 Idiopathic pulmonary fibrosis                               | 7             | 0.1          | 26            | 0.1          | 6            | 0.1          | 3            | 0.1          | 1            | 0.1          | 3            | 0.1          | 46            | 0.1          |
| 516.32 Idiopathic interstitial pneumonitis                         | 0             | 0.0          | 2             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 2             | 0.0          |
| 516.33 Acute interstitial pneumonitis                              | 2             | 0.0          | 2             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 4             | 0.0          |
| 516.34 Bronchiolitis interstitial lung dis                         | 0             | 0.0          | 4             | 0.0          | 0            | 0.0          | 1            | 0.0          | 1            | 0.1          | 0            | 0.0          | 6             | 0.0          |
| 516.35 Idiopathic lymphoid interstitial pneumonia                  | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 516.36 Cryptogenic organizing pneumonia                            | 0             | 0.0          | 2             | 0.0          | 0            | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 3             | 0.0          |
| 516.37 Desquamative interstitial pneumonia                         | 0             | 0.0          | 1             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1             | 0.0          |
| 516.8 Other specified alveolar and parietoalveolar pneumonopathies | 15            | 0.1          | 53            | 0.2          | 8            | 0.1          | 6            | 0.1          | 2            | 0.2          | 4            | 0.1          | 88            | 0.2          |
| 516.9 Unspecified alveolar and parietoalveolar pneumonopathy       | 12            | 0.1          | 43            | 0.2          | 5            | 0.1          | 3            | 0.1          | 0            | 0.0          | 4            | 0.1          | 67            | 0.1          |
| 518.82 Other pulmonary insufficiency, not elsewhere classified     | 173           | 1.7          | 696           | 2.6          | 134          | 1.7          | 47           | 0.8          | 20           | 1.9          | 40           | 1.1          | 1,110         | 2.0          |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

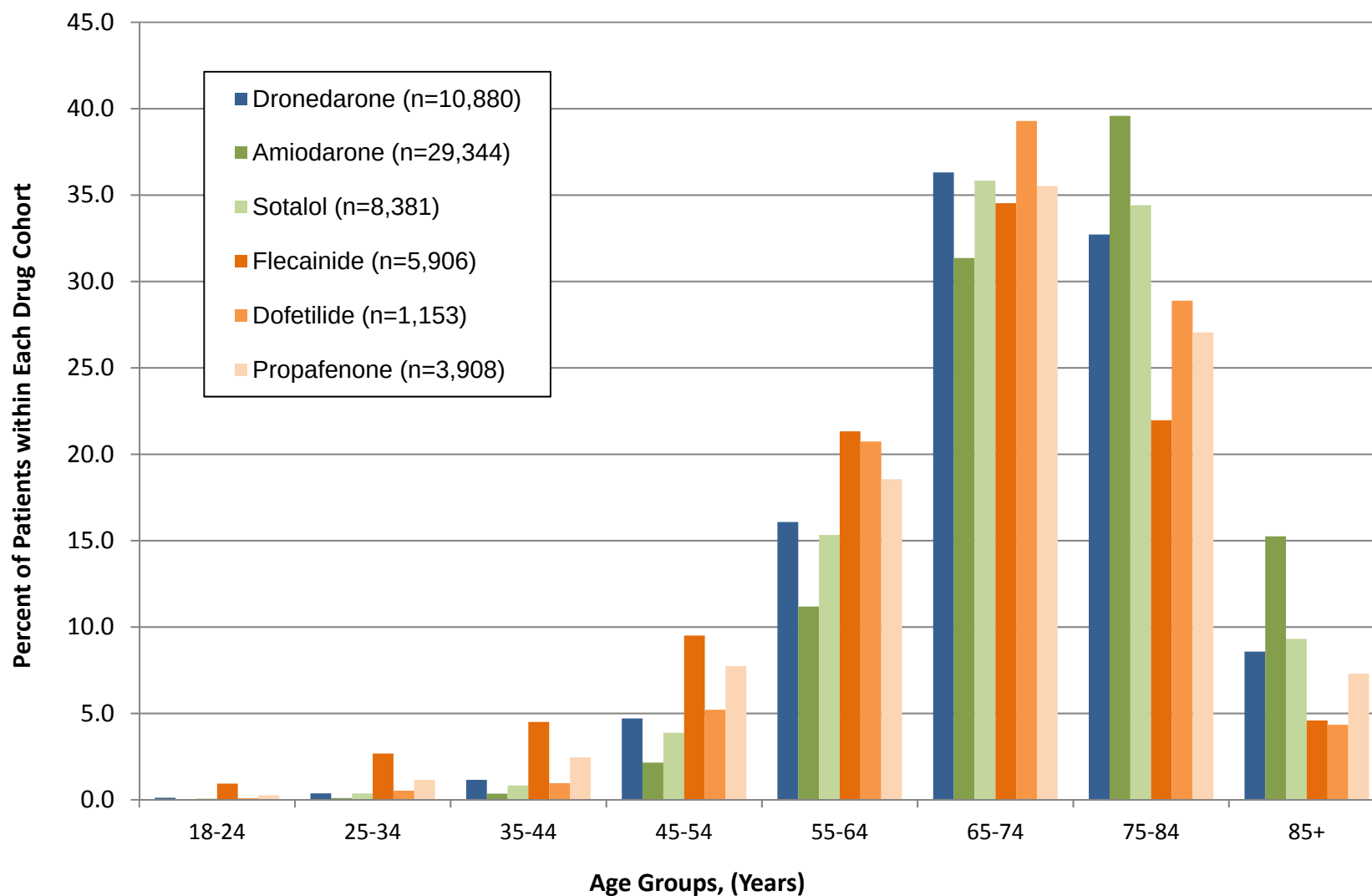
Note: Patient counts reflect the only first occurrence after the index date of a diagnosis code that defines ILD.

**Table 4. Age / Gender Demographics by Study Drug Cohort for 7/20/2009 - 3/31/2014;  
US DoD Database (2014Q1)**

| Age Groups            | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|-----------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                       | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total</b>          | <b>10,880</b> | <b>100.0</b> | <b>29,344</b> | <b>100.0</b> | <b>8,381</b> | <b>100.0</b> | <b>5,906</b> | <b>100.0</b> | <b>1,153</b> | <b>100.0</b> | <b>3,908</b> | <b>100.0</b> | <b>59,572</b> | <b>100.0</b> |
| 18-24                 | 12            | 0.1          | 10            | 0.0          | 6            | 0.1          | 55           | 0.9          | 1            | 0.1          | 10           | 0.3          | 94            | 0.2          |
| 25-34                 | 40            | 0.4          | 29            | 0.1          | 30           | 0.4          | 158          | 2.7          | 6            | 0.5          | 45           | 1.2          | 308           | 0.5          |
| 35-44                 | 125           | 1.1          | 103           | 0.4          | 69           | 0.8          | 266          | 4.5          | 11           | 1.0          | 96           | 2.5          | 670           | 1.1          |
| 45-54                 | 512           | 4.7          | 631           | 2.2          | 325          | 3.9          | 561          | 9.5          | 60           | 5.2          | 302          | 7.7          | 2,391         | 4.0          |
| 55-64                 | 1,749         | 16.1         | 3,282         | 11.2         | 1,284        | 15.3         | 1,259        | 21.3         | 239          | 20.7         | 725          | 18.6         | 8,538         | 14.3         |
| 65-74                 | 3,950         | 36.3         | 9,201         | 31.4         | 3,003        | 35.8         | 2,039        | 34.5         | 453          | 39.3         | 1,388        | 35.5         | 20,034        | 33.6         |
| 75-84                 | 3,559         | 32.7         | 11,615        | 39.6         | 2,884        | 34.4         | 1,297        | 22.0         | 333          | 28.9         | 1,057        | 27.0         | 20,745        | 34.8         |
| 85+                   | 933           | 8.6          | 4,473         | 15.2         | 780          | 9.3          | 271          | 4.6          | 50           | 4.3          | 285          | 7.3          | 6,792         | 11.4         |
| <b>Female</b>         | <b>5,052</b>  | <b>46.4</b>  | <b>11,893</b> | <b>40.5</b>  | <b>3,916</b> | <b>46.7</b>  | <b>3,002</b> | <b>50.8</b>  | <b>389</b>   | <b>33.7</b>  | <b>2,011</b> | <b>51.5</b>  | <b>26,263</b> | <b>44.1</b>  |
| 18-24                 | 3             | 0.1          | 1             | 0.0          | 4            | 0.1          | 9            | 0.3          | 1            | 0.3          | 4            | 0.2          | 22            | 0.1          |
| 25-34                 | 6             | 0.1          | 5             | 0.0          | 12           | 0.3          | 43           | 1.4          | 2            | 0.5          | 10           | 0.5          | 78            | 0.3          |
| 35-44                 | 24            | 0.5          | 27            | 0.2          | 22           | 0.6          | 63           | 2.1          | 3            | 0.8          | 15           | 0.7          | 154           | 0.6          |
| 45-54                 | 132           | 2.6          | 148           | 1.2          | 88           | 2.2          | 173          | 5.8          | 12           | 3.1          | 93           | 4.6          | 646           | 2.5          |
| 55-64                 | 639           | 12.6         | 895           | 7.5          | 431          | 11.0         | 558          | 18.6         | 59           | 15.2         | 295          | 14.7         | 2,877         | 11.0         |
| 65-74                 | 1,733         | 34.3         | 3,203         | 26.9         | 1,299        | 33.2         | 1,084        | 36.1         | 140          | 36.0         | 726          | 36.1         | 8,185         | 31.2         |
| 75-84                 | 1,925         | 38.1         | 5,060         | 42.5         | 1,537        | 39.2         | 870          | 29.0         | 147          | 37.8         | 666          | 33.1         | 10,205        | 38.9         |
| 85+                   | 590           | 11.7         | 2,554         | 21.5         | 523          | 13.4         | 202          | 6.7          | 25           | 6.4          | 202          | 10.0         | 4,096         | 15.6         |
| <b>Male</b>           | <b>5,828</b>  | <b>53.6</b>  | <b>17,451</b> | <b>59.5</b>  | <b>4,465</b> | <b>53.3</b>  | <b>2,904</b> | <b>49.2</b>  | <b>763</b>   | <b>66.2</b>  | <b>1,897</b> | <b>48.5</b>  | <b>33,308</b> | <b>55.9</b>  |
| 18-24                 | 9             | 0.2          | 9             | 0.1          | 2            | 0.0          | 46           | 1.6          | 0            | 0.0          | 6            | 0.3          | 72            | 0.2          |
| 25-34                 | 34            | 0.6          | 24            | 0.1          | 18           | 0.4          | 115          | 4.0          | 4            | 0.5          | 35           | 1.8          | 230           | 0.7          |
| 35-44                 | 101           | 1.7          | 76            | 0.4          | 47           | 1.1          | 203          | 7.0          | 8            | 1.0          | 81           | 4.3          | 516           | 1.5          |
| 45-54                 | 380           | 6.5          | 483           | 2.8          | 237          | 5.3          | 388          | 13.4         | 48           | 6.3          | 209          | 11.0         | 1,745         | 5.2          |
| 55-64                 | 1,110         | 19.0         | 2,387         | 13.7         | 853          | 19.1         | 701          | 24.1         | 180          | 23.6         | 430          | 22.7         | 5,661         | 17.0         |
| 65-74                 | 2,217         | 38.0         | 5,998         | 34.4         | 1,704        | 38.2         | 955          | 32.9         | 312          | 40.9         | 662          | 34.9         | 11,848        | 35.6         |
| 75-84                 | 1,634         | 28.0         | 6,555         | 37.6         | 1,347        | 30.2         | 427          | 14.7         | 186          | 24.4         | 391          | 20.6         | 10,540        | 31.6         |
| 85+                   | 343           | 5.9          | 1,919         | 11.0         | 257          | 5.8          | 69           | 2.4          | 25           | 3.3          | 83           | 4.4          | 2,696         | 8.1          |
| <b>Unknown Gender</b> | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>     | <b>0.1</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>      | <b>0.0</b>   |
| 65-74                 | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 100.0        | 0            | 0.0          | 1             | 100.0        |

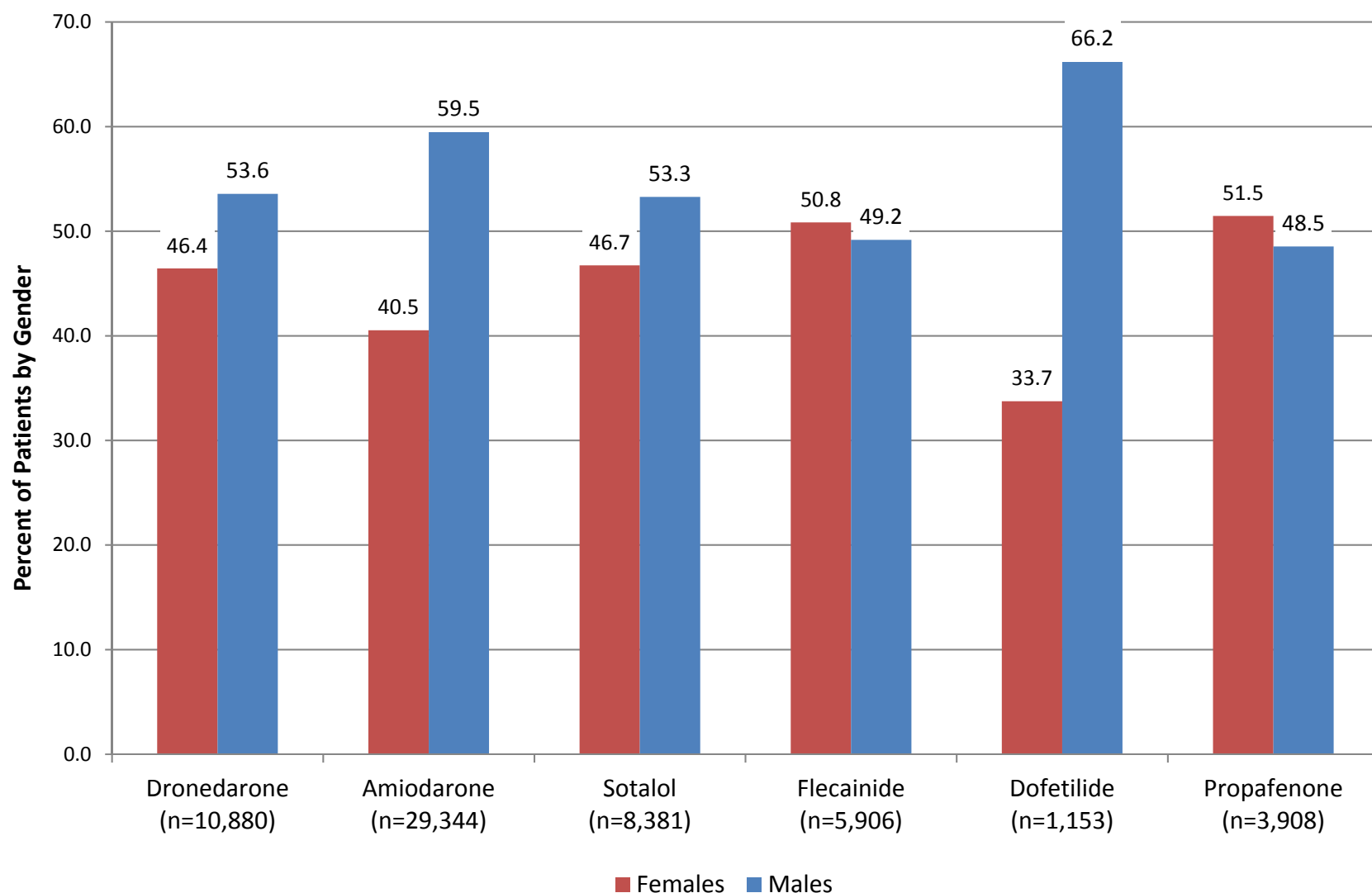


**Figure 1. Age Demographics of Study Drug Cohorts;  
US DoD Database: July 20, 2009 - March 31, 2014\***



\* Prior to screening for each outcome event.

**Figure 2. Gender Demographics of Study Drug Cohorts**  
**US DoD Database: July 20, 2009 - March 31, 2014\***



\* Prior to screening for each outcome event.

**Table 1. Number of Patients with a Study Drug of Interest between 7/20/2009 and 03/31/2014, End of Monitoring Period 06/30/2014, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Screening Description                                             | Dronedarone   |            | Amiodarone    |            | Sotalol       |            | Flecainide    |            | Dofetilide   |            | Propafenone   |            | Total          |            |
|-------------------------------------------------------------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|--------------|------------|---------------|------------|----------------|------------|
|                                                                   | N             | %          | N             | %          | N             | %          | N             | %          | N            | %          | N             | %          | N              | %          |
| <b>Assign the first study drug as the cohort</b>                  | <b>15,891</b> | <b>100</b> | <b>72,579</b> | <b>100</b> | <b>26,825</b> | <b>100</b> | <b>16,116</b> | <b>100</b> | <b>3,094</b> | <b>100</b> | <b>11,789</b> | <b>100</b> | <b>146,294</b> | <b>100</b> |
| Less patients without 365 days of eligibility prior to index date | 233           | 1%         | 751           | 1%         | 735           | 3%         | 653           | 4%         | 90           | 3%         | 302           | 3%         | 2,764          | 2%         |
| Less patients without AF in the year prior to index date          | 2,565         | 16%        | 20,553        | 28%        | 6,648         | 25%        | 4,722         | 29%        | 343          | 11%        | 2,826         | 24%        | 37,657         | 26%        |
| Less patients with the index drug in the year prior to index date | 0             | 0%         | 13,847        | 19%        | 9,274         | 35%        | 3,977         | 25%        | 1,300        | 42%        | 4,013         | 34%        | 32,411         | 22%        |
| Less patients with multiple study drugs on index date             | 2             | 0%         | 28            | 0%         | 0             | 0%         | 2             | 0%         | 0            | 0%         | 3             | 0%         | 35             | 0%         |
| Less patients with date of death preceding index date             | 4             | 0%         | 10            | 0%         | 4             | 0%         | 2             | 0%         | 0            | 0%         | 1             | 0%         | 21             | 0%         |
| Less patients below 18 years old on index date*                   | 0             | 0%         | 4             | 0%         | 2             | 0%         | 3             | 0%         | 0            | 0%         | 2             | 0%         | 11             | 0%         |
| Less patients with cancer or organ transplant in baseline period* | 2,197         | 14%        | 7,996         | 11%        | 1,764         | 7%         | 826           | 5%         | 204          | 7%         | 725           | 6%         | 13,712         | 9%         |
| Less patients with HIV in baseline period*                        | 2             | 0%         | 12            | 0%         | 2             | 0%         | 5             | 0%         | 1            | 0%         | 2             | 0%         | 24             | 0%         |
| Less patients with pregnancy codes prior and/or post index date*  | 8             | 0%         | 35            | 0%         | 14            | 0%         | 21            | 0%         | 2            | 0%         | 8             | 0%         | 88             | 0%         |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>10,880</b> | <b>68%</b> | <b>29,343</b> | <b>40%</b> | <b>8,382</b>  | <b>31%</b> | <b>5,905</b>  | <b>37%</b> | <b>1,154</b> | <b>37%</b> | <b>3,907</b>  | <b>33%</b> | <b>59,571</b>  | <b>41%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Serious Liver Injury/Disease (SLD) - Prior SLD Screening*</b> | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,343        | 40%        | 8,382        | 31%        | 5,905        | 37%        | 1,154        | 37%        | 3,907        | 33%        | 59,571        | 41%        |
| Less patients with SLD in baseline period                        | 460           | 3%         | 1,742         | 2%         | 444          | 2%         | 230          | 1%         | 68           | 2%         | 144          | 1%         | 3,088         | 2%         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                    | <b>10,420</b> | <b>66%</b> | <b>27,601</b> | <b>38%</b> | <b>7,938</b> | <b>30%</b> | <b>5,675</b> | <b>35%</b> | <b>1,086</b> | <b>35%</b> | <b>3,763</b> | <b>32%</b> | <b>56,483</b> | <b>39%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Interstitial Lung Disease (ILD) - Prior ILD Screening*</b>    | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,343        | 40%        | 8,382        | 31%        | 5,905        | 37%        | 1,154        | 37%        | 3,907        | 33%        | 59,571        | 41%        |
| Less patients with ILD in baseline period                        | 584           | 4%         | 2,654         | 4%         | 505          | 2%         | 173          | 1%         | 84           | 3%         | 187          | 2%         | 4,187         | 3%         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                    | <b>10,296</b> | <b>65%</b> | <b>26,689</b> | <b>37%</b> | <b>7,877</b> | <b>29%</b> | <b>5,732</b> | <b>36%</b> | <b>1,070</b> | <b>35%</b> | <b>3,720</b> | <b>32%</b> | <b>55,384</b> | <b>38%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

**Table 2. Number of Patients with at least One Serious Liver Injury/Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 through 06/30/2014; US DoD Database**

| Surveillance from 7/20/2009 - 6/30/2014                        | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|----------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                                                                | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total Patients</b>                                          | <b>10,420</b> | <b>100.0</b> | <b>27,601</b> | <b>100.0</b> | <b>7,938</b> | <b>100.0</b> | <b>5,675</b> | <b>100.0</b> | <b>1,086</b> | <b>100.0</b> | <b>3,763</b> | <b>100.0</b> | <b>56,483</b> | <b>100.0</b> |
| <b>Patients with ≥1 occurrence of SLD Diagnosis</b>            | <b>627</b>    | <b>6.0</b>   | <b>1,852</b>  | <b>6.7</b>   | <b>433</b>   | <b>5.5</b>   | <b>261</b>   | <b>4.6</b>   | <b>61</b>    | <b>5.6</b>   | <b>213</b>   | <b>5.7</b>   | <b>3,447</b>  | <b>6.1</b>   |
| <b>ICD-9-CM Diagnosis</b>                                      |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 277.4 Disorders of bilirubin excretion                         | 17            | 0.2          | 49            | 0.2          | 18           | 0.2          | 6            | 0.1          | 2            | 0.2          | 4            | 0.1          | 96            | 0.2          |
| 570 Acute and subacute necrosis of liver                       | 32            | 0.3          | 172           | 0.6          | 22           | 0.3          | 14           | 0.2          | 4            | 0.4          | 2            | 0.1          | 246           | 0.4          |
| 571.5 Cirrhosis of liver without mention of alcohol            | 39            | 0.4          | 124           | 0.4          | 25           | 0.3          | 10           | 0.2          | 6            | 0.6          | 15           | 0.4          | 219           | 0.4          |
| 572.2 Hepatic coma                                             | 8             | 0.1          | 37            | 0.1          | 2            | 0.0          | 0            | 0.0          | 1            | 0.1          | 4            | 0.1          | 52            | 0.1          |
| 572.4 Hepatorenal syndrome                                     | 3             | 0.0          | 11            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 15            | 0.0          |
| 572.8 Other sequelae of chronic liver disease                  | 8             | 0.1          | 31            | 0.1          | 5            | 0.1          | 3            | 0.1          | 1            | 0.1          | 2            | 0.1          | 50            | 0.1          |
| 573.0 Chronic passive congestion of liver                      | 3             | 0.0          | 44            | 0.2          | 6            | 0.1          | 2            | 0.0          | 0            | 0.0          | 2            | 0.1          | 57            | 0.1          |
| 573.3 Hepatitis, unspecified                                   | 37            | 0.4          | 134           | 0.5          | 29           | 0.4          | 12           | 0.2          | 4            | 0.4          | 19           | 0.5          | 235           | 0.4          |
| 573.8 Other specified disorders of liver                       | 239           | 2.3          | 511           | 1.9          | 172          | 2.2          | 104          | 1.8          | 19           | 1.7          | 71           | 1.9          | 1,116         | 2.0          |
| 573.9 Unspecified disorder of the liver                        | 47            | 0.5          | 160           | 0.6          | 33           | 0.4          | 22           | 0.4          | 7            | 0.6          | 30           | 0.8          | 299           | 0.5          |
| 782.4 Jaundice, unspecified                                    | 46            | 0.4          | 155           | 0.6          | 30           | 0.4          | 14           | 0.2          | 5            | 0.5          | 13           | 0.3          | 263           | 0.5          |
| 794.8 Nonspecific abnormal results of liver function test      | 164           | 1.6          | 495           | 1.8          | 110          | 1.4          | 78           | 1.4          | 14           | 1.3          | 49           | 1.3          | 910           | 1.6          |
| V42.7 Liver replaced by transplant                             | 1             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 5             | 0.0          |
| <b>ICD-9-CM Procedures</b>                                     |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver           | 6             | 0.1          | 21            | 0.1          | 3            | 0.0          | 3            | 0.1          | 0            | 0.0          | 1            | 0.0          | 34            | 0.1          |
| 50.12 Open biopsy of liver                                     | 1             | 0.0          | 1             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 4             | 0.0          |
| 50.13 Transjugular liver biopsy                                | 0             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 4             | 0.0          |
| 50.14 Laparoscopic liver biopsy                                | 5             | 0.0          | 1             | 0.0          | 0            | 0.0          | 1            | 0.0          | 1            | 0.1          | 1            | 0.0          | 9             | 0.0          |
| 50.5 Liver transplant                                          | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.51 Auxiliary liver transplant                               | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.59 Other transplant of liver                                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.91 Percutaneous aspiration of liver                         | 0             | 0.0          | 3             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 4             | 0.0          |
| <b>CPT® Procedures</b>                                         |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 47000 Biopsy of liver, needle: percutaneous                    | 8             | 0.1          | 21            | 0.1          | 5            | 0.1          | 4            | 0.1          | 0            | 0.0          | 2            | 0.1          | 40            | 0.1          |
| 47001 Biopsy of liver, needle: done at time or other           | 3             | 0.0          | 4             | 0.0          | 2            | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 10            | 0.0          |
| 47100 Biopsy of liver, wedge                                   | 2             | 0.0          | 5             | 0.0          | 1            | 0.0          | 1            | 0.0          | 1            | 0.1          | 0            | 0.0          | 10            | 0.0          |
| 47135 Liver allotransplantation, orthotopic, partial or whole  | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 47136 Liver allotransplantation, heterotopic, partial or whole | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 78205 Liver imaging (Spect)                                    | 0             | 0.0          | 1             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1             | 0.0          |
| 78206 Liver imaging (Spect), with vascular flow                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

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Note: Patient counts reflect the only the first occurrence after the index date of a diagnosis/procedure code that defines SLD.

**Table 3. Number of Patients with at least One Interstitial Lung Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 - 6/30/2014; US DoD Database**

| Surveillance from 7/20/2009 - 6/30/2014                            | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Total  |       |
|--------------------------------------------------------------------|-------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|--------|-------|
|                                                                    | N           | %     | N          | %     | N       | %     | N          | %     | N          | %     | N           | %     | N      | %     |
| Total patients                                                     | 10,296      | 100.0 | 26,689     | 100.0 | 7,877   | 100.0 | 5,732      | 100.0 | 1,070      | 100.0 | 3,720       | 100.0 | 55,384 | 100.0 |
| Patients with ≥ 1 occurrence of an ILD code                        | 575         | 5.6   | 2,035      | 7.6   | 450     | 5.7   | 197        | 3.4   | 65         | 6.1   | 159         | 4.3   | 3,481  | 6.3   |
| ICD-9-CM Diagnosis*                                                |             |       |            |       |         |       |            |       |            |       |             |       |        |       |
| 495.9 Unspecified allergic alveolitis and pneumonitis              | 7           | 0.1   | 18         | 0.1   | 3       | 0.0   | 1          | 0.0   | 1          | 0.1   | 3           | 0.1   | 33     | 0.1   |
| 515 Postinflammatory pulmonary fibrosis                            | 348         | 3.4   | 1,146      | 4.3   | 277     | 3.5   | 128        | 2.2   | 39         | 3.6   | 100         | 2.7   | 2,038  | 3.7   |
| 516.3 Idiopathic fibrosing alveolitis                              | 11          | 0.1   | 30         | 0.1   | 7       | 0.1   | 2          | 0.0   | 0          | 0.0   | 2           | 0.1   | 52     | 0.1   |
| 516.30 Idiopathic interstitial pneumonia unspec                    | 5           | 0.0   | 15         | 0.1   | 5       | 0.1   | 1          | 0.0   | 0          | 0.0   | 2           | 0.1   | 28     | 0.1   |
| 516.31 Idiopathic pulmonary fibrosis                               | 9           | 0.1   | 30         | 0.1   | 7       | 0.1   | 3          | 0.1   | 1          | 0.1   | 3           | 0.1   | 53     | 0.1   |
| 516.32 Idiopathich interstitial pneumonitis                        | 0           | 0.0   | 2          | 0.0   | 0       | 0.0   | 0          | 0.0   | 0          | 0.0   | 0           | 0.0   | 2      | 0.0   |
| 516.33 Acute interstitial pnemonitis                               | 2           | 0.0   | 2          | 0.0   | 0       | 0.0   | 0          | 0.0   | 0          | 0.0   | 0           | 0.0   | 4      | 0.0   |
| 516.34 Bronchiolitis interstitial lung dis                         | 0           | 0.0   | 5          | 0.0   | 1       | 0.0   | 1          | 0.0   | 1          | 0.1   | 0           | 0.0   | 8      | 0.0   |
| 516.35 Idiopathic lymphoid interstitial pneumonia                  | 0           | 0.0   | 0          | 0.0   | 0       | 0.0   | 0          | 0.0   | 0          | 0.0   | 0           | 0.0   | 0      | 0.0   |
| 516.36 Cryptogenic organizing pneumonia                            | 0           | 0.0   | 2          | 0.0   | 0       | 0.0   | 1          | 0.0   | 0          | 0.0   | 0           | 0.0   | 3      | 0.0   |
| 516.37 Desquamative interstitial pneumonia                         | 0           | 0.0   | 1          | 0.0   | 0       | 0.0   | 0          | 0.0   | 0          | 0.0   | 0           | 0.0   | 1      | 0.0   |
| 516.8 Other specified alveolar and parietoalveolar pneumonopathies | 17          | 0.2   | 55         | 0.2   | 10      | 0.1   | 7          | 0.1   | 2          | 0.2   | 4           | 0.1   | 95     | 0.2   |
| 516.9 Unspecified alveolar and parietoalveolar pneumonopathy       | 12          | 0.1   | 43         | 0.2   | 5       | 0.1   | 3          | 0.1   | 0          | 0.0   | 4           | 0.1   | 67     | 0.1   |
| 518.82 Other pulmonary insufficiency, not elsewhere classified     | 176         | 1.7   | 721        | 2.7   | 140     | 1.8   | 53         | 0.9   | 22         | 2.1   | 44          | 1.2   | 1,156  | 2.1   |

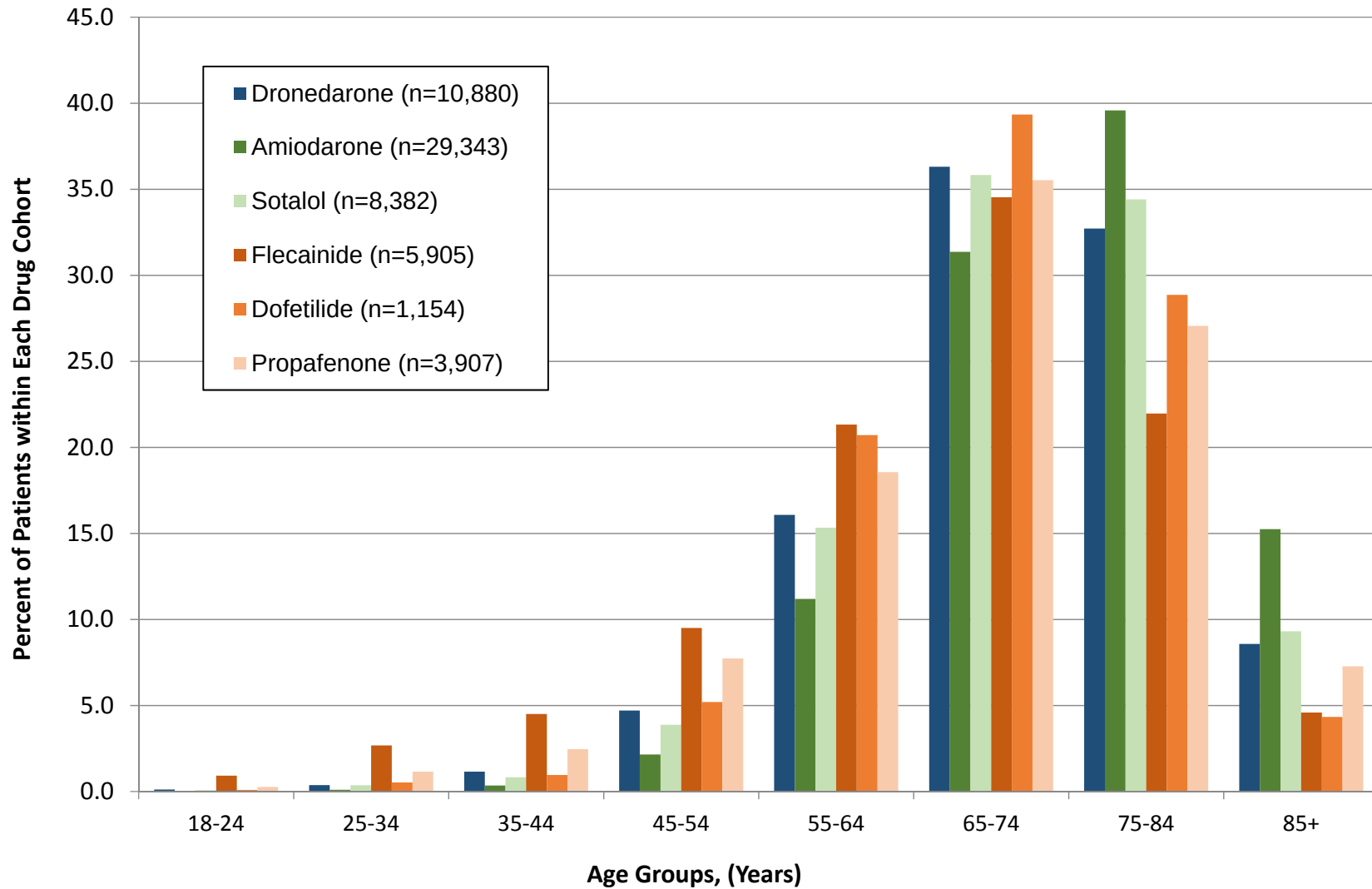
\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

Note: Patient counts reflect the only first occurrence after the index date of a diagnosis code that defines ILD.

**Table 4. Age / Gender Demographic of Patients (with a Study Drug of Interest between 7/20/2009 and 03/31/2014) by Study Drug Cohort; US DoD Database (2014Q2)**

| Age Groups            | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|-----------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                       | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total</b>          | <b>10,880</b> | <b>100.0</b> | <b>29,343</b> | <b>100.0</b> | <b>8,382</b> | <b>100.0</b> | <b>5,905</b> | <b>100.0</b> | <b>1,154</b> | <b>100.0</b> | <b>3,907</b> | <b>100.0</b> | <b>59,571</b> | <b>100.0</b> |
| 18-24                 | 12            | 0.1          | 10            | 0.0          | 6            | 0.1          | 54           | 0.9          | 1            | 0.1          | 10           | 0.3          | 93            | 0.2          |
| 25-34                 | 40            | 0.4          | 29            | 0.1          | 30           | 0.4          | 158          | 2.7          | 6            | 0.5          | 45           | 1.2          | 308           | 0.5          |
| 35-44                 | 125           | 1.1          | 102           | 0.3          | 69           | 0.8          | 266          | 4.5          | 11           | 1.0          | 96           | 2.5          | 669           | 1.1          |
| 45-54                 | 512           | 4.7          | 631           | 2.2          | 325          | 3.9          | 561          | 9.5          | 60           | 5.2          | 302          | 7.7          | 2,391         | 4.0          |
| 55-64                 | 1,749         | 16.1         | 3,282         | 11.2         | 1,285        | 15.3         | 1,259        | 21.3         | 239          | 20.7         | 725          | 18.6         | 8,539         | 14.3         |
| 65-74                 | 3,950         | 36.3         | 9,201         | 31.4         | 3,003        | 35.8         | 2,039        | 34.5         | 454          | 39.3         | 1,388        | 35.5         | 20,035        | 33.6         |
| 75-84                 | 3,559         | 32.7         | 11,615        | 39.6         | 2,884        | 34.4         | 1,297        | 22.0         | 333          | 28.9         | 1,057        | 27.1         | 20,745        | 34.8         |
| 85+                   | 933           | 8.6          | 4,473         | 15.2         | 780          | 9.3          | 271          | 4.6          | 50           | 4.3          | 284          | 7.3          | 6,791         | 11.4         |
| <b>Female</b>         | <b>5,052</b>  | <b>46.4</b>  | <b>11,892</b> | <b>40.5</b>  | <b>3,916</b> | <b>46.7</b>  | <b>3,001</b> | <b>50.8</b>  | <b>390</b>   | <b>33.8</b>  | <b>2,010</b> | <b>51.4</b>  | <b>26,261</b> | <b>44.1</b>  |
| 18-24                 | 3             | 0.1          | 1             | 0.0          | 4            | 0.1          | 8            | 0.3          | 1            | 0.3          | 4            | 0.2          | 21            | 0.1          |
| 25-34                 | 6             | 0.1          | 5             | 0.0          | 12           | 0.3          | 43           | 1.4          | 2            | 0.5          | 10           | 0.5          | 78            | 0.3          |
| 35-44                 | 24            | 0.5          | 26            | 0.2          | 22           | 0.6          | 63           | 2.1          | 3            | 0.8          | 15           | 0.7          | 153           | 0.6          |
| 45-54                 | 132           | 2.6          | 148           | 1.2          | 88           | 2.2          | 173          | 5.8          | 12           | 3.1          | 93           | 4.6          | 646           | 2.5          |
| 55-64                 | 639           | 12.6         | 895           | 7.5          | 431          | 11.0         | 558          | 18.6         | 59           | 15.1         | 295          | 14.7         | 2,877         | 11.0         |
| 65-74                 | 1,733         | 34.3         | 3,203         | 26.9         | 1,299        | 33.2         | 1,084        | 36.1         | 141          | 36.2         | 726          | 36.1         | 8,186         | 31.2         |
| 75-84                 | 1,925         | 38.1         | 5,060         | 42.5         | 1,537        | 39.2         | 870          | 29.0         | 147          | 37.7         | 666          | 33.1         | 10,205        | 38.9         |
| 85+                   | 590           | 11.7         | 2,554         | 21.5         | 523          | 13.4         | 202          | 6.7          | 25           | 6.4          | 201          | 10.0         | 4,095         | 15.6         |
| <b>Male</b>           | <b>5,828</b>  | <b>53.6</b>  | <b>17,451</b> | <b>59.5</b>  | <b>4,466</b> | <b>53.3</b>  | <b>2,904</b> | <b>49.2</b>  | <b>763</b>   | <b>66.1</b>  | <b>1,897</b> | <b>48.6</b>  | <b>33,309</b> | <b>55.9</b>  |
| 18-24                 | 9             | 0.2          | 9             | 0.1          | 2            | 0.0          | 46           | 1.6          | 0            | 0.0          | 6            | 0.3          | 72            | 0.2          |
| 25-34                 | 34            | 0.6          | 24            | 0.1          | 18           | 0.4          | 115          | 4.0          | 4            | 0.5          | 35           | 1.8          | 230           | 0.7          |
| 35-44                 | 101           | 1.7          | 76            | 0.4          | 47           | 1.1          | 203          | 7.0          | 8            | 1.0          | 81           | 4.3          | 516           | 1.5          |
| 45-54                 | 380           | 6.5          | 483           | 2.8          | 237          | 5.3          | 388          | 13.4         | 48           | 6.3          | 209          | 11.0         | 1,745         | 5.2          |
| 55-64                 | 1,110         | 19.0         | 2,387         | 13.7         | 854          | 19.1         | 701          | 24.1         | 180          | 23.6         | 430          | 22.7         | 5,662         | 17.0         |
| 65-74                 | 2,217         | 38.0         | 5,998         | 34.4         | 1,704        | 38.2         | 955          | 32.9         | 312          | 40.9         | 662          | 34.9         | 11,848        | 35.6         |
| 75-84                 | 1,634         | 28.0         | 6,555         | 37.6         | 1,347        | 30.2         | 427          | 14.7         | 186          | 24.4         | 391          | 20.6         | 10,540        | 31.6         |
| 85+                   | 343           | 5.9          | 1,919         | 11.0         | 257          | 5.8          | 69           | 2.4          | 25           | 3.3          | 83           | 4.4          | 2,696         | 8.1          |
| <b>Unknown Gender</b> | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1.0</b>   | <b>0.1</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>      | <b>0.0</b>   |
| 65-74                 | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 100.0        | 0            | 0.0          | 1             | 100.0        |

**Figure 1. Age Demographic of Patients (with a Study Drug of Interest between 7/20/2009 and 03/31/2014) by Study Drug Cohort\*; US DoD Database (2014Q2)**



\* Prior to screening for each outcome event.

**Table 1. Number of Patients with a Study Drug of Interest between 7/20/2009 and 03/31/2014, End of Monitoring Period 09/30/2014, By Study Drug Cohort and Screening Criteria; US DoD Database**

| Screening Description                                             | Dronedarone   |            | Amiodarone    |            | Sotalol       |            | Flecainide    |            | Dofetilide   |            | Propafenone   |            | Total          |            |
|-------------------------------------------------------------------|---------------|------------|---------------|------------|---------------|------------|---------------|------------|--------------|------------|---------------|------------|----------------|------------|
|                                                                   | N             | %          | N             | %          | N             | %          | N             | %          | N            | %          | N             | %          | N              | %          |
| <b>Assign the first study drug as the cohort</b>                  | <b>15,891</b> | <b>100</b> | <b>72,581</b> | <b>100</b> | <b>26,826</b> | <b>100</b> | <b>16,117</b> | <b>100</b> | <b>3,094</b> | <b>100</b> | <b>11,790</b> | <b>100</b> | <b>146,299</b> | <b>100</b> |
| Less patients without 365 days of eligibility prior to index date | 233           | 1%         | 751           | 1%         | 735           | 3%         | 654           | 4%         | 90           | 3%         | 302           | 3%         | 2,765          | 2%         |
| Less patients without AF in the year prior to index date          | 2,565         | 16%        | 20,555        | 28%        | 6,648         | 25%        | 4,722         | 29%        | 343          | 11%        | 2,827         | 24%        | 37,660         | 26%        |
| Less patients with the index drug in the year prior to index date | 0             | 0%         | 13,847        | 19%        | 9,274         | 35%        | 3,977         | 25%        | 1,300        | 42%        | 4,013         | 34%        | 32,411         | 22%        |
| Less patients with multiple study drugs on index date             | 2             | 0%         | 28            | 0%         | 0             | 0%         | 2             | 0%         | 0            | 0%         | 3             | 0%         | 35             | 0%         |
| Less patients with date of death preceding index date             | 4             | 0%         | 10            | 0%         | 4             | 0%         | 2             | 0%         | 0            | 0%         | 1             | 0%         | 21             | 0%         |
| Less patients below 18 years old on index date*                   | 0             | 0%         | 4             | 0%         | 2             | 0%         | 3             | 0%         | 0            | 0%         | 2             | 0%         | 11             | 0%         |
| Less patients with cancer or organ transplant in baseline period* | 2,197         | 14%        | 7,996         | 11%        | 1,765         | 7%         | 826           | 5%         | 204          | 7%         | 725           | 6%         | 13,713         | 9%         |
| Less patients with HIV in baseline period*                        | 2             | 0.0        | 12            | 0.0        | 2             | 0.0        | 5             | 0.0        | 1            | 0.0        | 2             | 0.0        | 24             | 0.0        |
| Less patients with pregnancy codes prior and/or post index date*  | 8             | 0%         | 37            | 0%         | 14            | 0%         | 21            | 0%         | 2            | 0%         | 8             | 0%         | 90             | 0%         |
| <b>Remaining patients prior to screening for Outcome Cohorts</b>  | <b>10,880</b> | <b>68%</b> | <b>29,341</b> | <b>40%</b> | <b>8,382</b>  | <b>31%</b> | <b>5,905</b>  | <b>37%</b> | <b>1,154</b> | <b>37%</b> | <b>3,907</b>  | <b>33%</b> | <b>59,569</b>  | <b>41%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Serious Liver Injury/Disease (SLD) - Prior SLD Screening*</b> | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,341        | 40%        | 8,382        | 31%        | 5,905        | 37%        | 1,154        | 37%        | 3,907        | 33%        | 59,569        | 41%        |
| Less patients with SLD in baseline period                        | 460           | 3%         | 1,742         | 2%         | 444          | 2%         | 230          | 1%         | 68           | 2%         | 144          | 1%         | 3,088         | 2%         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                    | <b>10,420</b> | <b>66%</b> | <b>27,599</b> | <b>38%</b> | <b>7,938</b> | <b>30%</b> | <b>5,675</b> | <b>35%</b> | <b>1,086</b> | <b>35%</b> | <b>3,763</b> | <b>32%</b> | <b>56,481</b> | <b>39%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol

| <b>Interstitial Lung Disease (ILD) - Prior ILD Screening*</b>    | Dronedarone   |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide   |            | Propafenone  |            | Total         |            |
|------------------------------------------------------------------|---------------|------------|---------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|---------------|------------|
| Remaining patients prior to identifying outcome analysis cohorts | 10,880        | 68%        | 29,341        | 40%        | 8,382        | 31%        | 5,905        | 37%        | 1,154        | 37%        | 3,907        | 33%        | 59,569        | 41%        |
| Less patients with ILD in baseline period                        | 584           | 4%         | 2,654         | 4%         | 505          | 2%         | 173          | 1.1        | 84           | 2.7        | 187          | 1.6        | 4,187         | 3%         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                    | <b>10,296</b> | <b>65%</b> | <b>26,687</b> | <b>37%</b> | <b>7,877</b> | <b>29%</b> | <b>5,732</b> | <b>36%</b> | <b>1,070</b> | <b>35%</b> | <b>3,720</b> | <b>32%</b> | <b>55,382</b> | <b>38%</b> |

\* Additional screening to reflect Epidemiologic Study Protocol



**Table 2. Number of Patients with at least One Serious Liver Injury/Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 through 09/30/2014; US DoD Database**

| Surveillance from 7/20/2009 - 9/30/2014                        | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|----------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                                                                | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total Patients</b>                                          | <b>10,420</b> | <b>100.0</b> | <b>27,599</b> | <b>100.0</b> | <b>7,938</b> | <b>100.0</b> | <b>5,675</b> | <b>100.0</b> | <b>1,086</b> | <b>100.0</b> | <b>3,763</b> | <b>100.0</b> | <b>56,481</b> | <b>100.0</b> |
| <b>Patients with ≥1 occurrence of SLD Diagnosis</b>            | <b>655</b>    | <b>6.3</b>   | <b>1,936</b>  | <b>7.0</b>   | <b>456</b>   | <b>5.7</b>   | <b>271</b>   | <b>4.8</b>   | <b>64</b>    | <b>5.9</b>   | <b>219</b>   | <b>5.8</b>   | <b>3,601</b>  | <b>6.4</b>   |
| <b>ICD-9-CM Diagnosis</b>                                      |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 277.4 Disorders of bilirubin excretion                         | 18            | 0.2          | 50            | 0.2          | 18           | 0.2          | 6            | 0.1          | 2            | 0.2          | 4            | 0.1          | 98            | 0.2          |
| 570 Acute and subacute necrosis of liver                       | 34            | 0.3          | 178           | 0.6          | 23           | 0.3          | 15           | 0.3          | 4            | 0.4          | 2            | 0.1          | 256           | 0.5          |
| 571.5 Cirrhosis of liver without mention of alcohol            | 43            | 0.4          | 131           | 0.5          | 29           | 0.4          | 11           | 0.2          | 6            | 0.6          | 16           | 0.4          | 236           | 0.4          |
| 572.2 Hepatic coma                                             | 8             | 0.1          | 40            | 0.1          | 2            | 0.0          | 0            | 0.0          | 1            | 0.1          | 4            | 0.1          | 55            | 0.1          |
| 572.4 Hepatorenal syndrome                                     | 4             | 0.0          | 12            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 17            | 0.0          |
| 572.8 Other sequelae of chronic liver disease                  | 8             | 0.1          | 34            | 0.1          | 5            | 0.1          | 3            | 0.1          | 1            | 0.1          | 2            | 0.1          | 53            | 0.1          |
| 573.0 Chronic passive congestion of liver                      | 3             | 0.0          | 47            | 0.2          | 6            | 0.1          | 2            | 0.0          | 0            | 0.0          | 2            | 0.1          | 60            | 0.1          |
| 573.3 Hepatitis, unspecified                                   | 37            | 0.4          | 137           | 0.5          | 29           | 0.4          | 14           | 0.2          | 4            | 0.4          | 19           | 0.5          | 240           | 0.4          |
| 573.8 Other specified disorders of liver                       | 248           | 2.4          | 537           | 1.9          | 180          | 2.3          | 105          | 1.9          | 20           | 1.8          | 74           | 2.0          | 1,164         | 2.1          |
| 573.9 Unspecified disorder of the liver                        | 50            | 0.5          | 167           | 0.6          | 35           | 0.4          | 24           | 0.4          | 8            | 0.7          | 30           | 0.8          | 314           | 0.6          |
| 782.4 Jaundice, unspecified                                    | 50            | 0.5          | 164           | 0.6          | 33           | 0.4          | 15           | 0.3          | 6            | 0.6          | 14           | 0.4          | 282           | 0.5          |
| 794.8 Nonspecific abnormal results of liver function test      | 171           | 1.6          | 513           | 1.9          | 114          | 1.4          | 81           | 1.4          | 14           | 1.3          | 50           | 1.3          | 943           | 1.7          |
| V42.7 Liver replaced by transplant                             | 1             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 5             | 0.0          |
| <b>ICD-9-CM Procedures</b>                                     |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver           | 7             | 0.1          | 21            | 0.1          | 4            | 0.1          | 3            | 0.1          | 0            | 0.0          | 1            | 0.0          | 36            | 0.1          |
| 50.12 Open biopsy of liver                                     | 1             | 0.0          | 2             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 5             | 0.0          |
| 50.13 Transjugular liver biopsy                                | 0             | 0.0          | 3             | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 4             | 0.0          |
| 50.14 Laparoscopic liver biopsy                                | 5             | 0.0          | 1             | 0.0          | 0            | 0.0          | 1            | 0.0          | 1            | 0.1          | 1            | 0.0          | 9             | 0.0          |
| 50.5 Liver transplant                                          | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.51 Auxiliary liver transplant                               | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.59 Other transplant of liver                                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 50.91 Percutaneous aspiration of liver                         | 0             | 0.0          | 3             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 0.0          | 4             | 0.0          |
| <b>CPT® Procedures</b>                                         |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 47000 Biopsy of liver, needle: percutaneous                    | 8             | 0.1          | 21            | 0.1          | 6            | 0.1          | 4            | 0.1          | 0            | 0.0          | 2            | 0.1          | 41            | 0.1          |
| 47001 Biopsy of liver, needle: done at time or other           | 3             | 0.0          | 4             | 0.0          | 3            | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 11            | 0.0          |
| 47100 Biopsy of liver, wedge                                   | 2             | 0.0          | 6             | 0.0          | 1            | 0.0          | 1            | 0.0          | 1            | 0.1          | 0            | 0.0          | 11            | 0.0          |
| 47135 Liver allotransplantation, orthotopic, partial or whole  | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 47136 Liver allotransplantation, heterotopic, partial or whole | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 78205 Liver imaging (Spect)                                    | 0             | 0.0          | 1             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1             | 0.0          |
| 78206 Liver imaging (Spect), with vascular flow                | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |

\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

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Note: Patient counts reflect the only first occurrence after the index date of a diagnosis/procedure code that defines SLD.

**Table 3. Number of Patients with at least One Interstitial Lung Disease Definition Code Post Index Date by Study Cohort between 7/20/2009 - 9/30/2014; US DoD Database**

| Surveillance from 7/20/2009 - 9/30/2014                            | Dronedarone   |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|--------------------------------------------------------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                                                                    | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total patients</b>                                              | <b>10,296</b> | <b>100.0</b> | <b>26,687</b> | <b>100.0</b> | <b>7,877</b> | <b>100.0</b> | <b>5,732</b> | <b>100.0</b> | <b>1,070</b> | <b>100.0</b> | <b>3,720</b> | <b>100.0</b> | <b>55,382</b> | <b>100.0</b> |
| <b>Patients with ≥ 1 occurrence of an ILD code</b>                 | <b>592</b>    | <b>5.7</b>   | <b>2,127</b>  | <b>8.0</b>   | <b>484</b>   | <b>6.1</b>   | <b>212</b>   | <b>3.7</b>   | <b>69</b>    | <b>6.4</b>   | <b>165</b>   | <b>4.4</b>   | <b>3,649</b>  | <b>6.6</b>   |
| <b>ICD-9-CM Diagnosis*</b>                                         |               |              |               |              |              |              |              |              |              |              |              |              |               |              |
| 495.9 Unspecified allergic alveolitis and pneumonitis              | 7             | 0.1          | 18            | 0.1          | 3            | 0.0          | 1            | 0.0          | 1            | 0.1          | 3            | 0.1          | 33            | 0.1          |
| 515 Postinflammatory pulmonary fibrosis                            | 358           | 3.5          | 1,200         | 4.5          | 297          | 3.8          | 135          | 2.4          | 43           | 4.0          | 103          | 2.8          | 2,136         | 3.9          |
| 516.3 Idiopathic fibrosing alveolitis                              | 11            | 0.1          | 30            | 0.1          | 7            | 0.1          | 2            | 0.0          | 0            | 0.0          | 2            | 0.1          | 52            | 0.1          |
| 516.30 Idiopathic interstitial pneumonia unspec                    | 5             | 0.0          | 15            | 0.1          | 5            | 0.1          | 1            | 0.0          | 0            | 0.0          | 2            | 0.1          | 28            | 0.1          |
| 516.31 Idiopathic pulmonary fibrosis                               | 9             | 0.1          | 32            | 0.1          | 9            | 0.1          | 3            | 0.1          | 1            | 0.1          | 3            | 0.1          | 57            | 0.1          |
| 516.32 Idiopathic interstitial pneumonitis                         | 0             | 0.0          | 2             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 2             | 0.0          |
| 516.33 Acute interstitial pneumonitis                              | 2             | 0.0          | 3             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 5             | 0.0          |
| 516.34 Bronchiolitis interstitial lung dis                         | 0             | 0.0          | 5             | 0.0          | 1            | 0.0          | 1            | 0.0          | 1            | 0.1          | 1            | 0.0          | 9             | 0.0          |
| 516.35 Idiopathic lymphoid interstitial pneumonia                  | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0             | 0.0          |
| 516.36 Cryptogenic organizing pneumonia                            | 0             | 0.0          | 3             | 0.0          | 0            | 0.0          | 1            | 0.0          | 0            | 0.0          | 0            | 0.0          | 4             | 0.0          |
| 516.37 Desquamative interstitial pneumonia                         | 0             | 0.0          | 1             | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 0            | 0.0          | 1             | 0.0          |
| 516.8 Other specified alveolar and parietoalveolar pneumonopathies | 19            | 0.2          | 56            | 0.2          | 12           | 0.2          | 7            | 0.1          | 2            | 0.2          | 4            | 0.1          | 100           | 0.2          |
| 516.9 Unspecified alveolar and parietoalveolar pneumonopathy       | 12            | 0.1          | 43            | 0.2          | 5            | 0.1          | 4            | 0.1          | 0            | 0.0          | 5            | 0.1          | 69            | 0.1          |
| 518.82 Other pulmonary insufficiency, not elsewhere classified     | 181           | 1.8          | 754           | 2.8          | 151          | 1.9          | 60           | 1.0          | 22           | 2.1          | 45           | 1.2          | 1,213         | 2.2          |

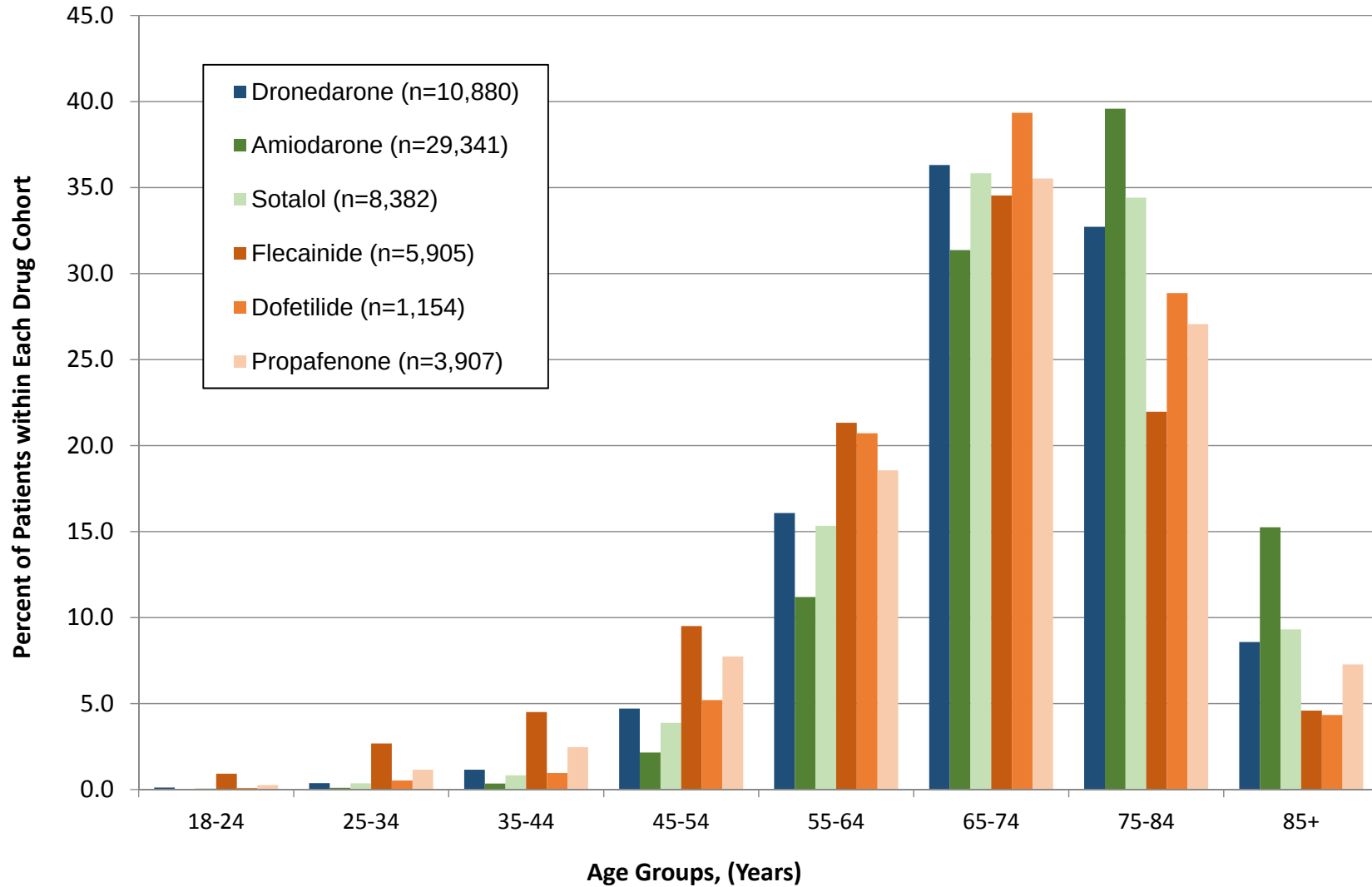
\* Rows are not mutually exclusive. Percentage is calculated as number of patients for the individual code divided by the number of patients with an outcome.

Note: Patient counts reflect the only the first occurrence after the index date of a diagnosis code that defines ILD.

**Table 4. Age / Gender Demographic of Patients (with a Study Drug of Interest between 7/20/2009 and 03/31/2014) by Study Drug Cohort; US DoD Database (2014Q3)**

| Age Groups            | Dronedaronone |              | Amiodarone    |              | Sotalol      |              | Flecainide   |              | Dofetilide   |              | Propafenone  |              | Total         |              |
|-----------------------|---------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|
|                       | N             | %            | N             | %            | N            | %            | N            | %            | N            | %            | N            | %            | N             | %            |
| <b>Total</b>          | <b>10,880</b> | <b>100.0</b> | <b>29,341</b> | <b>100.0</b> | <b>8,382</b> | <b>100.0</b> | <b>5,905</b> | <b>100.0</b> | <b>1,154</b> | <b>100.0</b> | <b>3,907</b> | <b>100.0</b> | <b>59,569</b> | <b>100.0</b> |
| 18-24                 | 12            | 0.1          | 10            | 0.0          | 6            | 0.1          | 54           | 0.9          | 1            | 0.1          | 10           | 0.3          | 93            | 0.2          |
| 25-34                 | 40            | 0.4          | 29            | 0.1          | 30           | 0.4          | 158          | 2.7          | 6            | 0.5          | 45           | 1.2          | 308           | 0.5          |
| 35-44                 | 125           | 1.1          | 102           | 0.3          | 69           | 0.8          | 266          | 4.5          | 11           | 1.0          | 96           | 2.5          | 669           | 1.1          |
| 45-54                 | 512           | 4.7          | 631           | 2.2          | 325          | 3.9          | 561          | 9.5          | 60           | 5.2          | 302          | 7.7          | 2,391         | 4.0          |
| 55-64                 | 1,749         | 16.1         | 3,282         | 11.2         | 1,285        | 15.3         | 1,259        | 21.3         | 239          | 20.7         | 725          | 18.6         | 8,539         | 14.3         |
| 65-74                 | 3,950         | 36.3         | 9,201         | 31.4         | 3,003        | 35.8         | 2,039        | 34.5         | 454          | 39.3         | 1,388        | 35.5         | 20,035        | 33.6         |
| 75-84                 | 3,559         | 32.7         | 11,613        | 39.6         | 2,884        | 34.4         | 1,297        | 22.0         | 333          | 28.9         | 1,057        | 27.1         | 20,743        | 34.8         |
| 85+                   | 933           | 8.6          | 4,473         | 15.2         | 780          | 9.3          | 271          | 4.6          | 50           | 4.3          | 284          | 7.3          | 6,791         | 11.4         |
| <b>Female</b>         | <b>5,052</b>  | <b>46.4</b>  | <b>11,890</b> | <b>40.5</b>  | <b>3,916</b> | <b>46.7</b>  | <b>3,001</b> | <b>50.8</b>  | <b>390</b>   | <b>33.8</b>  | <b>2,010</b> | <b>51.4</b>  | <b>26,259</b> | <b>44.1</b>  |
| 18-24                 | 3             | 0.1          | 1             | 0.0          | 4            | 0.1          | 8            | 0.3          | 1            | 0.3          | 4            | 0.2          | 21            | 0.1          |
| 25-34                 | 6             | 0.1          | 5             | 0.0          | 12           | 0.3          | 43           | 1.4          | 2            | 0.5          | 10           | 0.5          | 78            | 0.3          |
| 35-44                 | 24            | 0.5          | 26            | 0.2          | 22           | 0.6          | 63           | 2.1          | 3            | 0.8          | 15           | 0.7          | 153           | 0.6          |
| 45-54                 | 132           | 2.6          | 148           | 1.2          | 88           | 2.2          | 173          | 5.8          | 12           | 3.1          | 93           | 4.6          | 646           | 2.5          |
| 55-64                 | 639           | 12.6         | 895           | 7.5          | 431          | 11.0         | 558          | 18.6         | 59           | 15.1         | 295          | 14.7         | 2,877         | 11.0         |
| 65-74                 | 1,733         | 34.3         | 3,203         | 26.9         | 1,299        | 33.2         | 1,084        | 36.1         | 141          | 36.2         | 726          | 36.1         | 8,186         | 31.2         |
| 75-84                 | 1,925         | 38.1         | 5,058         | 42.5         | 1,537        | 39.2         | 870          | 29.0         | 147          | 37.7         | 666          | 33.1         | 10,203        | 38.9         |
| 85+                   | 590           | 11.7         | 2,554         | 21.5         | 523          | 13.4         | 202          | 6.7          | 25           | 6.4          | 201          | 10.0         | 4,095         | 15.6         |
| <b>Male</b>           | <b>5,828</b>  | <b>53.6</b>  | <b>17,451</b> | <b>59.5</b>  | <b>4,466</b> | <b>53.3</b>  | <b>2,904</b> | <b>49.2</b>  | <b>763</b>   | <b>66.1</b>  | <b>1,897</b> | <b>48.6</b>  | <b>33,309</b> | <b>55.9</b>  |
| 18-24                 | 9             | 0.2          | 9             | 0.1          | 2            | 0.0          | 46           | 1.6          | 0            | 0.0          | 6            | 0.3          | 72            | 0.2          |
| 25-34                 | 34            | 0.6          | 24            | 0.1          | 18           | 0.4          | 115          | 4.0          | 4            | 0.5          | 35           | 1.8          | 230           | 0.7          |
| 35-44                 | 101           | 1.7          | 76            | 0.4          | 47           | 1.1          | 203          | 7.0          | 8            | 1.0          | 81           | 4.3          | 516           | 1.5          |
| 45-54                 | 380           | 6.5          | 483           | 2.8          | 237          | 5.3          | 388          | 13.4         | 48           | 6.3          | 209          | 11.0         | 1,745         | 5.2          |
| 55-64                 | 1,110         | 19.0         | 2,387         | 13.7         | 854          | 19.1         | 701          | 24.1         | 180          | 23.6         | 430          | 22.7         | 5,662         | 17.0         |
| 65-74                 | 2,217         | 38.0         | 5,998         | 34.4         | 1,704        | 38.2         | 955          | 32.9         | 312          | 40.9         | 662          | 34.9         | 11,848        | 35.6         |
| 75-84                 | 1,634         | 28.0         | 6,555         | 37.6         | 1,347        | 30.2         | 427          | 14.7         | 186          | 24.4         | 391          | 20.6         | 10,540        | 31.6         |
| 85+                   | 343           | 5.9          | 1,919         | 11.0         | 257          | 5.8          | 69           | 2.4          | 25           | 3.3          | 83           | 4.4          | 2,696         | 8.1          |
| <b>Unknown Gender</b> | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>    | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1.0</b>   | <b>0.1</b>   | <b>0.0</b>   | <b>0.0</b>   | <b>1</b>      | <b>0.0</b>   |
| 65-74                 | 0             | 0.0          | 0             | 0.0          | 0            | 0.0          | 0            | 0.0          | 1            | 100.0        | 0            | 0.0          | 1             | 100.0        |

**Figure 1. Age Demographic of Patients (with a Study Drug of Interest between 7/20/2009 and 03/31/2014) by Study Drug Cohort\*; US DoD Database (2014Q3)**



\* Prior to screening for each outcome event.

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## **APPENDIX 5. HIRD DATABASE – QUARTERLY REPORTS OF PATIENT ACCRUALS**

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**Retrospective Period (July 2009 - December 2011)**

|                                                                             |
|-----------------------------------------------------------------------------|
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| Table 1. New Index Dronedaronone and Comparator User Counts (Patient-Level) |
| Table 2. Serious Liver Injury Counts, By Cohort                             |
| Table 3. Interstitial Lung Disease Counts, By Cohort                        |

**Retrospective Period (July 2009 - December 2011)**

| <b>Table 1. New Index Dronedarone and Comparator User Counts (Patient-Level)<sup>1,2</sup></b> |                                                                              |                                                  |                                                                                                           |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <b>Cohorts</b>                                                                                 | <b>Patients Identified During Retrospective Period (Jul 2009 – Dec 2011)</b> | <b>New Index Users Current Monitoring Period</b> | <b>Total Patients Identified Through End of Current Monitoring Period (Retro + New Users)<sup>1</sup></b> |
| Dronedarone                                                                                    | 5,421                                                                        |                                                  | 5,421                                                                                                     |
| Amiodarone                                                                                     | 9,534                                                                        |                                                  | 9,534                                                                                                     |
| Sotalol                                                                                        | 3,269                                                                        |                                                  | 3,269                                                                                                     |
| Flecainide                                                                                     | 2,584                                                                        |                                                  | 2,584                                                                                                     |
| Dofetilide                                                                                     | 573                                                                          |                                                  | 573                                                                                                       |
| Propafenone                                                                                    | 1,928                                                                        |                                                  | 1,928                                                                                                     |
| <b>Total</b>                                                                                   | <b>23,309</b>                                                                |                                                  | <b>23,309</b>                                                                                             |
| 1. This Table will be completed each quarter during the prospective count.                     |                                                                              |                                                  |                                                                                                           |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.        |                                                                              |                                                  |                                                                                                           |



Retrospective Period (July 2009 - December 2011)

| Table 2. Serious Liver Injury Counts, By Cohort <sup>1,2,3,4</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------|----------------|-------------------|-------------------|--------------------|--------------|--------------|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Events                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Patients Identified During Retrospective Period<br>(Jul 2009 – Dec 2011) |                   |                |                   |                   |                    |              |              | Serious Liver Injury<br>Occurrences Identified<br>During Current<br>Monitoring Period | Total Serious Liver Injury<br>Occurrences Identified Through<br>End of Current Monitoring Period<br>(Retro + New Users) <sup>1</sup> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <u>Dronedarone</u>                                                       | <u>Amiodarone</u> | <u>Sotalol</u> | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u> | <u>Total</u> | <u>Total</u>                                                                          | <u>Total</u>                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 5,421                                                                    | 9,534             | 3,269          | 2,584             | 573               | 1,928              | 23,309       |              |                                                                                       |                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | N (%)                                                                    | N (%)             | N (%)          | N (%)             | N (%)             | N (%)              | N (%)        | N (%)        | N (%)                                                                                 | N (%)                                                                                                                                |
| Total                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 405 (7.5)                                                                | 1,009 (10.6)      | 262 (8.0)      | 124 (4.8)         | 47 (8.2)          | 132 (6.8)          | 1,979 (8.5)  |              |                                                                                       | 1,979 (8.5)                                                                                                                          |
| Serious Liver Injury                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
| <u>ICD-9-CM Diagnoses</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
| Other disorders of liver (ICD-9-CM 573.xx)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 122 (2.3)                                                                | 271 (2.8)         | 82 (2.5)       | 48 (1.9)          | 11 (1.9)          | 48 (2.5)           | 582 (2.5)    |              |                                                                                       | 582 (2.5)                                                                                                                            |
| Other or nonspecified abnormal serum levels (ICD-9-CM 790.5x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 68 (1.3)                                                                 | 160 (1.7)         | 59 (1.8)       | 14 (0.5)          | 11 (1.9)          | 14 (0.7)           | 326 (1.4)    |              |                                                                                       | 326 (1.4)                                                                                                                            |
| Other specified disorders of liver (ICD-9-CM 573.8x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 65 (1.2)                                                                 | 144 (1.5)         | 46 (1.4)       | 30 (1.2)          | 6 (1.0)           | 30 (1.6)           | 321 (1.4)    |              |                                                                                       | 321 (1.4)                                                                                                                            |
| Ascites (ICD-9-CM 789.5x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 39 (0.7)                                                                 | 205 (2.2)         | 28 (0.9)       | 8 (0.3)           | 5 (0.9)           | 17 (0.9)           | 302 (1.3)    |              |                                                                                       | 302 (1.3)                                                                                                                            |
| Nonspecific abnormal results of liver function test (ICD-9-CM 794.8x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 63 (1.2)                                                                 | 124 (1.3)         | 32 (1.0)       | 16 (0.6)          | 6 (1.0)           | 17 (0.9)           | 258 (1.1)    |              |                                                                                       | 258 (1.1)                                                                                                                            |
| Nonspecific elevation of levels of transaminase or LDH (ICD-9-CM 790.4x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 74 (1.4)                                                                 | 102 (1.1)         | 37 (1.1)       | 19 (0.7)          | 7 (1.2)           | 18 (0.9)           | 257 (1.1)    |              |                                                                                       | 257 (1.1)                                                                                                                            |
| Unspecified disorder of liver (ICD-9-CM 573.9x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 36 (0.7)                                                                 | 74 (0.8)          | 23 (0.7)       | 10 (0.4)          | 4 (0.7)           | 10 (0.5)           | 157 (0.7)    |              |                                                                                       | 157 (0.7)                                                                                                                            |
| Hepatitis, unspecified (ICD-9-CM 573.3x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 21 (0.4)                                                                 | 48 (0.5)          | 12 (0.4)       | 9 (0.3)           | 3 (0.5)           | 7 (0.4)            | 100 (0.4)    |              |                                                                                       | 100 (0.4)                                                                                                                            |
| Cirrhosis of liver without mention of alcohol (ICD-9-CM 571.5x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 10 (0.2)                                                                 | 41 (0.4)          | 13 (0.4)       | 7 (0.3)           | 2 (0.3)           | 5 (0.3)            | 78 (0.3)     |              |                                                                                       | 78 (0.3)                                                                                                                             |
| Jaundice, unspecified (ICD-9-CM 782.4x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 10 (0.2)                                                                 | 42 (0.4)          | 10 (0.3)       | 5 (0.2)           | 1 (0.2)           | 4 (0.2)            | 72 (0.3)     |              |                                                                                       | 72 (0.3)                                                                                                                             |
| Hepatomegaly (ICD-9-CM 789.1x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 20 (0.4)                                                                 | 28 (0.3)          | 6 (0.2)        | 7 (0.3)           | 2 (0.3)           | 3 (0.2)            | 66 (0.3)     |              |                                                                                       | 66 (0.3)                                                                                                                             |
| Acute and subacute necrosis of liver (ICD-9-CM 570.xx)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9 (0.2)                                                                  | 31 (0.3)          | 6 (0.2)        | 3 (0.1)           | 2 (0.3)           | 2 (0.1)            | 53 (0.2)     |              |                                                                                       | 53 (0.2)                                                                                                                             |
| Chronic passive congestion of liver (ICD-9-CM 573.0x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2 (0.0)                                                                  | 13 (0.1)          | 2 (0.1)        | -                 | -                 | 1 (0.1)            | 18 (0.1)     |              |                                                                                       | 18 (0.1)                                                                                                                             |
| Hepatic coma (ICD-9-CM 572.2x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 1 (0.0)                                                                  | 11 (0.1)          | 1 (0.0)        | -                 | -                 | 1 (0.1)            | 14 (0.1)     |              |                                                                                       | 14 (0.1)                                                                                                                             |
| Hepatorenal syndrome (ICD-9-CM 572.4x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1 (0.0)                                                                  | 2 (0.0)           | -              | -                 | -                 | -                  | 3 (0.0)      |              |                                                                                       | 3 (0.0)                                                                                                                              |
| Biliuria (ICD-9-CM 791.4x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                                                        | 1 (0.0)           | 1 (0.0)        | 1 (0.0)           | -                 | -                  | 3 (0.0)      |              |                                                                                       | 3 (0.0)                                                                                                                              |
| Hepatic infarction (ICD-9-CM 573.4x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| <u>ICD-9-CM Procedures</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
| Closed (percutaneous) [needle] biopsy of liver (ICD-9-CM 50.11)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | -                                                                        | 5 (0.1)           | -              | -                 | -                 | 2 (0.1)            | 7 (0.0)      |              |                                                                                       | 7 (0.0)                                                                                                                              |
| Laparoscopic liver biopsy (ICD-9-CM 50.14)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                                                        | 3 (0.0)           | 1 (0.0)        | -                 | -                 | -                  | 4 (0.0)      |              |                                                                                       | 4 (0.0)                                                                                                                              |
| Percutaneous aspiration of liver (ICD-9-CM 50.91)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | -                                                                        | 1 (0.0)           | -              | -                 | -                 | 1 (0.1)            | 2 (0.0)      |              |                                                                                       | 2 (0.0)                                                                                                                              |
| Open biopsy of liver (ICD-9-CM 50.12)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Transjugular liver biopsy (ICD-9-CM 50.13)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Liver transplant (ICD-9-CM 50.5x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Auxiliary liver transplant (ICD-9-CM 50.51)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Other transplant of liver (ICD-9-CM 50.59)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| <u>CPT Procedures</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
| Biopsy of liver, needle; percutaneous (CPT 47000)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 1 (0.0)                                                                  | 7 (0.1)           | 1 (0.0)        | 1 (0.0)           | 1 (0.2)           | 1 (0.1)            | 12 (0.1)     |              |                                                                                       | 12 (0.1)                                                                                                                             |
| Biopsy of liver, wedge (CPT 47100)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | -                                                                        | 1 (0.0)           | -              | -                 | -                 | 2 (0.1)            | 3 (0.0)      |              |                                                                                       | 3 (0.0)                                                                                                                              |
| Biopsy of liver, needle; done at time of other major procedure (CPT 47001)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                                                        | 1 (0.0)           | 1 (0.0)        | -                 | -                 | -                  | 2 (0.0)      |              |                                                                                       | 2 (0.0)                                                                                                                              |
| Liver imaging (SPECT, CPT 78205)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | -                                                                        | -                 | -              | 1 (0.0)           | -                 | -                  | 1 (0.0)      |              |                                                                                       | 1 (0.0)                                                                                                                              |
| Liver allotransplantation; orthotopic, partial or whole, (CPT 47135)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Liver allotransplantation; heterotopic, partial or whole, (CPT 47136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| Liver imaging (SPECT); with vascular flow (CPT 78206)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | -                                                                        | -                 | -              | -                 | -                 | -                  | -            |              |                                                                                       | -                                                                                                                                    |
| <u>Laboratory Test Values</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |
| Elevation of alanine transaminase levels, 3x higher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6 (0.1)                                                                  | 20 (0.2)          | 3 (0.1)        | -                 | 1 (0.2)           | 1 (0.1)            | 31 (0.1)     |              |                                                                                       | 31 (0.1)                                                                                                                             |
| Elevation of aspartate transaminase levels, 3x higher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1 (0.0)                                                                  | 7 (0.1)           | 1 (0.0)        | 1 (0.0)           | -                 | 2 (0.1)            | 12 (0.1)     |              |                                                                                       | 12 (0.1)                                                                                                                             |
| Elevation of bilirubin level, 1.5x higher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 1 (0.0)                                                                  | 3 (0.0)           | 3 (0.1)        | 2 (0.1)           | -                 | -                  | 9 (0.0)      |              |                                                                                       | 9 (0.0)                                                                                                                              |
| <div>1. This Table will be completed each quarter during the prospective count.</div> <div>2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all serious liver injury cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.</div> <div>3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.</div> <div>4. Percentages are reported as the number of patients identified with the listed code divided by the total number of patients identified as new index users in the cohort.</div> |                                                                          |                   |                |                   |                   |                    |              |              |                                                                                       |                                                                                                                                      |

Retrospective Period (July 2009 - December 2011)

| Table 3. Interstitial Lung Disease Counts, By Cohort <sup>1,2,3,4</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                          |                            |                         |                            |                          |                             |                        |  |                                                                                                            |                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------|-------------------------|----------------------------|--------------------------|-----------------------------|------------------------|--|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Events                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Patients Identified During Retrospective Period<br>(Jul 2009 – Dec 2011) |                            |                         |                            |                          |                             |                        |  | Interstitial Lung Disease<br>Occurrences Identified<br>During Current<br>Monitoring Period<br><u>Total</u> | Total Interstitial Lung Disease<br>Occurrences Identified Through End of<br>Current Monitoring Period<br>(Retro + New Users) <sup>1</sup><br><u>Total</u> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <u>Dronedarone</u><br>5,421                                              | <u>Amiodarone</u><br>9,534 | <u>Sotalol</u><br>3,269 | <u>Flecainide</u><br>2,584 | <u>Dofetilide</u><br>573 | <u>Propafenone</u><br>1,928 | <u>Total</u><br>23,309 |  |                                                                                                            |                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <i>N (%)</i>                                                             | <i>N (%)</i>               | <i>N (%)</i>            | <i>N (%)</i>               | <i>N (%)</i>             | <i>N (%)</i>                | <i>N (%)</i>           |  |                                                                                                            |                                                                                                                                                           |
| Total                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 197 (3.6)                                                                | 371 (3.9)                  | 104 (3.2)               | 37 (1.4)                   | 12 (2.1)                 | 42 (2.2)                    | 763 (3.3)              |  |                                                                                                            | 763 (3.3)                                                                                                                                                 |
| Interstitial lung disease                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                          |                            |                         |                            |                          |                             |                        |  |                                                                                                            |                                                                                                                                                           |
| Postinflammatory pulmonary fibrosis (ICD-9-CM 515.xx)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 161 (3.0)                                                                | 293 (3.1)                  | 82 (2.5)                | 28 (1.1)                   | 9 (1.6)                  | 34 (1.8)                    | 607 (2.6)              |  |                                                                                                            | 607 (2.6)                                                                                                                                                 |
| Idiopathic fibrosing alveolitis (ICD-9-CM 516.3x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 21 (0.4)                                                                 | 28 (0.3)                   | 9 (0.3)                 | 3 (0.1)                    | 3 (0.5)                  | 7 (0.4)                     | 71 (0.3)               |  |                                                                                                            | 71 (0.3)                                                                                                                                                  |
| Unspecified alveolar and parietoalveolar pneumonopathy (ICD-9-CM 516.9x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 13 (0.2)                                                                 | 31 (0.3)                   | 8 (0.2)                 | 3 (0.1)                    | - -                      | - -                         | 55 (0.2)               |  |                                                                                                            | 55 (0.2)                                                                                                                                                  |
| Other specified alveolar and parietoalveolar pneumonopathies (ICD-9-CM 516.8x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 7 (0.1)                                                                  | 20 (0.2)                   | 7 (0.2)                 | 2 (0.1)                    | - -                      | 1 (0.1)                     | 37 (0.2)               |  |                                                                                                            | 37 (0.2)                                                                                                                                                  |
| Unspecified allergic alveolitis and pneumonitis (ICD-9-CM 495.9x)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | - -                                                                      | 7 (0.1)                    | 3 (0.1)                 | 1 (0.0)                    | - -                      | 2 (0.1)                     | 13 (0.1)               |  |                                                                                                            | 13 (0.1)                                                                                                                                                  |
| <div>1. This Table will be completed each quarter during the prospective count.</div> <div>2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all interstitial lung disease cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.</div> <div>3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.</div> <div>4. Percentages are reported as the number of patients identified with the listed code divided by the total number of patients identified as new index users in the cohort.</div> |                                                                          |                            |                         |                            |                          |                             |                        |  |                                                                                                            |                                                                                                                                                           |

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Table 2. Serious Liver Injury Counts, By Cohort, HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Table 3. Interstitial Lung Disease Counts, By Cohort, HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Table 4. Age Distribution of Index Users, By Gender and Cohort, Through End of Current Period (Jul 2009 - Apr 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Figure 1. Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Apr 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

**Table 1. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD)<sup>SM</sup> 1,2,3**

| Patients                                                                                        | Dronedarone  |               | Amlodarone   |               | Sotalol      |               | Flecainide   |               | Dofetilide |              | Propafenone  |              | Total         |        |
|-------------------------------------------------------------------------------------------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|------------|--------------|--------------|--------------|---------------|--------|
|                                                                                                 | N            | (%)           | N            | (%)           | N            | (%)           | N            | (%)           | N          | (%)          | N            | (%)          | N             | (%)    |
| <b>Total patients identified through end of current period, Jul 2009 - Apr 2012<sup>4</sup></b> | <b>5,257</b> | <b>(22.3)</b> | <b>9,610</b> | <b>(40.8)</b> | <b>3,307</b> | <b>(14.0)</b> | <b>2,782</b> | <b>(11.8)</b> | <b>576</b> | <b>(2.4)</b> | <b>2,009</b> | <b>(8.5)</b> | <b>23,541</b> |        |
| Patients identified during retrospective period, Jul 2009 - Dec 2011 <sup>4</sup>               | 4,918        | (93.6)        | 8,167        | (85.0)        | 2,839        | (85.8)        | 2,348        | (84.4)        | 482        | (83.7)       | 1,721        | (85.7)       | 20,475        | (87.0) |
| New index patients identified during current period, Jan 2012 - Apr 2012                        | 339          | (6.4)         | 1,443        | (15.0)        | 468          | (14.2)        | 434          | (15.6)        | 94         | (16.3)       | 288          | (14.3)       | 3,066         | (13.0) |

1. This Table will be completed each quarter during the prospective count.

2. Only the index study drug will be counted, therefore a patient is only counted once.

3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.

4. Eligibility criteria were reassessed for patients identified during the retrospective period and only those still eligible are included.

Table 2. Serious Liver Injury Counts, By Cohort, HealthCore Integrated Research Database (HIRD) <sup>1,2,3</sup>

| Table 2. Serious Liver Injury Counts, by Cohort, HealthCore Integrated Research Database (HIRD) <sup>1,2,3,4</sup> |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
|--------------------------------------------------------------------------------------------------------------------|--|------------------------------------------------------------------------------------------------------------------------------|------------|-----------|------------|------------|-------------|-------------|------------|------------|----------|------------|------------------------------------------------------------------------------------------------------------------------|-------------|-----------|------------|--------------|-----------|------------|------------|-------------|-------------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|--|--|--|--|--|
| Events                                                                                                             |  | Serious Liver Injury Occurrences Among Patients Identified During Retrospective Period <sup>4</sup><br>(Jul 2009 – Dec 2011) |            |           |            |            |             |             |            |            |          |            | Serious Liver Injury Occurrences Among Patients Identified During Current Period <sup>4</sup><br>(Jan 2012 – Apr 2012) |             |           |            |              |           |            |            |             |             |          | Total Serious Liver Injury Occurrences Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 – Apr 2012)<br>(Retrospective + Current Period) |  |  |  |  |  |  |  |  |  |  |
|                                                                                                                    |  | Patients                                                                                                                     |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
|                                                                                                                    |  | Donepezium                                                                                                                   | Amiodarone | Sotalol   | Fluoxetine | Dofetilide | Propafenone | Total       | Donepezium | Amiodarone | Sotalol  | Fluoxetine | Dofetilide                                                                                                             | Propafenone | Total     | Donepezium | Amiodarone   | Sotalol   | Fluoxetine | Dofetilide | Propafenone | Total       |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
|                                                                                                                    |  | N (%)                                                                                                                        | N (%)      | N (%)     | N (%)      | N (%)      | N (%)       | N (%)       | N (%)      | N (%)      | N (%)    | N (%)      | N (%)                                                                                                                  | N (%)       | N (%)     | N (%)      | N (%)        | N (%)     | N (%)      | N (%)      | N (%)       | N (%)       |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Total <sup>5</sup>                                                                                                 |  | 417 (8.5)                                                                                                                    | 959 (11.7) | 261 (9.2) | 132 (5.6)  | 44 (9.1)   | 124 (7.2)   | 1,937 (9.5) | 9 (2.7)    | 59 (4.1)   | 14 (3.0) | 4 (0.9)    | 2 (2.1)                                                                                                                | 5 (1.7)     | 93 (3.0)  | 426 (8.1)  | 1,018 (10.6) | 275 (8.3) | 136 (4.9)  | 46 (8.0)   | 129 (6.4)   | 2,030 (8.6) |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Serious Liver Injury <sup>6</sup>                                                                                  |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| ICD-9-CM Diagnoses                                                                                                 |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 570.xx Acute and subacute necrosis of liver                                                                        |  | 11 (2.6)                                                                                                                     | 38 (4.0)   | 4 (1.5)   | 4 (3.0)    | 2 (4.5)    | 1 (0.8)     | 60 (3.1)    | - (0.0)    | 1 (1.7)    | 3 (21.4) | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | 4 (4.3)    | 11 (2.6)     | 39 (3.8)  | 7 (2.5)    | 4 (2.9)    | 2 (4.3)     | 1 (0.8)     | 64 (3.2) |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 571.5x Cirrhosis of liver without mention of alcohol                                                               |  | 13 (3.1)                                                                                                                     | 36 (3.8)   | 13 (5.0)  | 7 (5.3)    | 2 (4.5)    | 4 (3.2)     | 75 (3.8)    | - (0.0)    | 4 (6.8)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | 4 (4.3)    | 13 (3.1)     | 40 (3.9)  | 13 (4.7)   | 7 (5.1)    | 2 (4.3)     | 4 (3.1)     | 79 (3.8) |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 572.2x Hepatic coma                                                                                                |  | 1 (0.2)                                                                                                                      | 10 (1.0)   | 1 (0.4)   | - (0.0)    | - (0.0)    | - (0.0)     | 2 (1.6)     | 14 (0.7)   | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | 1 (0.2)      | 10 (1.0)  | 1 (0.4)    | - (0.0)    | - (0.0)     | 2 (1.6)     | 14 (0.7) |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 572.4x Hepatorenal syndrome                                                                                        |  | 1 (0.2)                                                                                                                      | 3 (0.3)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | 4 (0.2)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | 1 (0.2)      | 3 (0.3)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | 4 (0.2)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.xx Other disorders of liver                                                                                    |  | 127 (30.5)                                                                                                                   | 271 (28.3) | 77 (29.5) | 47 (35.6)  | 11 (25.0)  | 41 (33.1)   | 574 (29.6)  | 2 (22.2)   | 13 (22.0)  | 1 (7.1)  | 1 (25.0)   | 2 (100.0)                                                                                                              | 1 (20.0)    | 20 (21.5) | 129 (30.3) | 284 (27.9)   | 78 (28.4) | 48 (35.3)  | 13 (28.3)  | 42 (32.6)   | 594 (29.3)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.0x Chronic passive congestion of liver                                                                         |  | 2 (0.5)                                                                                                                      | 14 (1.5)   | 2 (0.8)   | - (0.0)    | - (0.0)    | 1 (0.8)     | 19 (1.0)    | - (0.0)    | 1 (1.7)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | 2 (0.5)    | 15 (1.5)     | 2 (0.7)   | - (0.0)    | - (0.0)    | 1 (0.8)     | 20 (1.0)    |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.3x Hepatitis, unspecified                                                                                      |  | 18 (4.3)                                                                                                                     | 47 (4.9)   | 12 (4.6)  | 9 (6.8)    | 2 (4.5)    | 5 (4.0)     | 93 (4.8)    | 1 (11.1)   | 6 (10.2)   | - (0.0)  | 1 (25.0)   | - (0.0)                                                                                                                | - (0.0)     | 8 (8.6)   | 19 (4.5)   | 53 (5.2)     | 12 (4.4)  | 10 (7.4)   | 2 (4.3)    | 5 (3.9)     | 101 (5.0)   |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.4x Hepatic infarction                                                                                          |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.8x Other specified disorders of liver                                                                          |  | 71 (17.0)                                                                                                                    | 142 (14.8) | 40 (15.3) | 30 (22.7)  | 7 (15.9)   | 27 (21.8)   | 317 (16.4)  | 1 (11.1)   | 4 (6.8)    | 1 (7.1)  | - (0.0)    | 1 (50.0)                                                                                                               | 1 (20.0)    | 8 (8.6)   | 72 (16.9)  | 146 (14.3)   | 41 (14.9) | 30 (22.1)  | 8 (17.4)   | 28 (21.7)   | 325 (16.0)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 573.9x Unspecified disorder of liver                                                                               |  | 38 (9.1)                                                                                                                     | 75 (7.8)   | 24 (9.2)  | 8 (6.1)    | 4 (9.1)    | 8 (6.5)     | 157 (8.1)   | - (0.0)    | 2 (3.4)    | - (0.0)  | - (0.0)    | 1 (50.0)                                                                                                               | - (0.0)     | 3 (3.2)   | 38 (8.9)   | 77 (7.6)     | 24 (8.7)  | 8 (5.9)    | 5 (10.9)   | 8 (6.2)     | 160 (7.9)   |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 782.4x Jaundice, unspecified                                                                                       |  | 8 (1.9)                                                                                                                      | 38 (4.0)   | 9 (3.4)   | 6 (4.5)    | 1 (2.3)    | 5 (4.0)     | 67 (3.5)    | - (0.0)    | 1 (1.7)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 1 (20.0)  | 2 (2.2)    | 8 (1.9)      | 39 (3.8)  | 9 (3.3)    | 6 (4.4)    | 1 (2.2)     | 6 (4.7)     | 69 (3.4) |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 789.1x Hepatomegaly                                                                                                |  | 22 (5.3)                                                                                                                     | 28 (2.9)   | 7 (2.7)   | 8 (6.1)    | 3 (6.8)    | 4 (3.2)     | 72 (3.7)    | - (0.0)    | 1 (1.7)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 1 (20.0)  | 2 (2.2)    | 22 (5.2)     | 29 (2.8)  | 7 (2.5)    | 8 (5.9)    | 3 (6.5)     | 5 (3.9)     | 74 (3.6) |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 789.5x Ascites                                                                                                     |  | 36 (8.6)                                                                                                                     | 186 (19.4) | 27 (10.3) | 9 (6.8)    | 5 (11.4)   | 10 (8.1)    | 273 (14.1)  | - (0.0)    | 9 (15.3)   | - (0.0)  | 1 (25.0)   | - (0.0)                                                                                                                | - (0.0)     | 10 (10.8) | 36 (8.5)   | 195 (19.2)   | 27 (9.8)  | 10 (7.4)   | 5 (10.9)   | 10 (7.8)    | 283 (13.9)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 790.4x Nonspecific elevation of levels of transaminase or LDH                                                      |  | 76 (18.2)                                                                                                                    | 103 (10.7) | 33 (12.6) | 19 (14.4)  | 5 (11.4)   | 21 (16.9)   | 257 (13.3)  | 3 (33.3)   | 8 (13.6)   | 2 (14.3) | - (0.0)    | - (0.0)                                                                                                                | 1 (20.0)    | 14 (15.1) | 79 (18.5)  | 111 (10.9)   | 35 (12.7) | 19 (14.0)  | 5 (10.9)   | 22 (17.1)   | 271 (13.3)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 790.5x Other or nonspecified abnormal serum levels                                                                 |  | 65 (15.6)                                                                                                                    | 144 (15.0) | 61 (23.4) | 16 (12.1)  | 11 (25.0)  | 13 (10.5)   | 310 (16.0)  | 2 (22.2)   | 15 (25.4)  | 4 (28.6) | 2 (50.0)   | - (0.0)                                                                                                                | 1 (20.0)    | 24 (25.8) | 67 (15.7)  | 159 (15.6)   | 65 (23.6) | 18 (13.2)  | 11 (23.9)  | 14 (10.9)   | 334 (16.5)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 791.4x Biliary                                                                                                     |  | - (0.0)                                                                                                                      | 1 (0.1)    | - (0.0)   | 1 (0.8)    | - (0.0)    | - (0.0)     | 2 (0.1)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | 1 (0.1)   | - (0.0)    | 1 (0.7)    | - (0.0)     | - (0.0)     | 2 (0.3)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 794.8x Nonspecific abnormal results of liver function test                                                         |  | 67 (16.1)                                                                                                                    | 116 (12.1) | 38 (14.6) | 17 (12.9)  | 5 (11.4)   | 20 (16.1)   | 263 (13.6)  | 2 (22.2)   | 9 (15.3)   | 2 (14.3) | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 13 (14.0) | 69 (16.2)  | 125 (12.3)   | 40 (14.5) | 17 (12.5)  | 5 (10.9)   | 20 (15.5)   | 276 (13.6)  |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| ICD-9-CM Procedures                                                                                                |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                                                               |  | - (0.0)                                                                                                                      | 5 (0.5)    | - (0.0)   | - (0.0)    | - (0.0)    | 2 (1.6)     | 7 (0.4)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | 5 (0.5)   | - (0.0)    | - (0.0)    | - (0.0)     | 2 (1.6)     | 7 (0.3)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.12 Open biopsy of liver                                                                                         |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.13 Transjugular liver biopsy                                                                                    |  | - (0.0)                                                                                                                      | 1 (0.1)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | 1 (0.1)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | 1 (0.1)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | 1 (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.14 Laparoscopic liver biopsy                                                                                    |  | - (0.0)                                                                                                                      | 2 (0.2)    | 1 (0.4)   | - (0.0)    | - (0.0)    | - (0.0)     | 3 (0.2)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | 2 (0.2)   | 1 (0.4)    | - (0.0)    | - (0.0)     | - (0.0)     | 3 (0.3)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.5x Liver transplant                                                                                             |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.51 Auxiliary liver transplant                                                                                   |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.59 Other transplant of liver                                                                                    |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| 50.91 Percutaneous aspiration of liver                                                                             |  | - (0.0)                                                                                                                      | 1 (0.1)    | - (0.0)   | - (0.0)    | - (0.0)    | 1 (0.8)     | 2 (0.1)     | - (0.0)    | - (0.0)    | 1 (7.1)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 1 (1.1)   | - (0.0)    | 1 (0.1)      | 1 (0.4)   | - (0.0)    | - (0.0)    | 1 (0.8)     | 3 (0.3)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT Procedures                                                                                                     |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 47000 Biopsy of liver, needle; percutaneous                                                                    |  | 1 (0.2)                                                                                                                      | 6 (0.6)    | 1 (0.4)   | 1 (0.8)    | 1 (2.3)    | - (0.0)     | 10 (0.5)    | - (0.0)    | 1 (1.7)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 1 (1.1)   | 1 (0.2)    | 7 (0.7)      | 1 (0.4)   | 1 (0.7)    | 1 (2.2)    | - (0.0)     | 11 (0.5)    |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 47001 Biopsy of liver, needle; done at time of other major pro                                                 |  | - (0.0)                                                                                                                      | 1 (0.1)    | 1 (0.4)   | - (0.0)    | - (0.0)    | - (0.0)     | 2 (0.1)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | 1 (0.1)      | 1 (0.4)   | - (0.0)    | - (0.0)    | - (0.0)     | 2 (0.3)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 47100 Biopsy of liver, wedge                                                                                   |  | - (0.0)                                                                                                                      | 1 (0.1)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | 2 (1.6)     | 3 (0.2)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | 1 (0.1)      | - (0.0)   | - (0.0)    | - (0.0)    | 2 (1.6)     | 3 (0.3)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole                                                  |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole                                                 |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 78205 Liver imaging (SPECT)                                                                                    |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | 1 (0.8)    | - (0.0)    | - (0.0)     | 1 (0.1)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | 1 (0.7)    | - (0.0)     | - (0.0)     | 1 (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| CPT 78206 Liver imaging (SPECT); with vascular flow                                                                |  | - (0.0)                                                                                                                      | - (0.0)    | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | - (0.0)    | - (0.0)      | - (0.0)   | - (0.0)    | - (0.0)    | - (0.0)     | - (0.0)     | - (0.0)  |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Laboratory Test Values                                                                                             |  |                                                                                                                              |            |           |            |            |             |             |            |            |          |            |                                                                                                                        |             |           |            |              |           |            |            |             |             |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Elevation of alanine transaminase levels, 3x higher                                                                |  | 6 (1.4)                                                                                                                      | 19 (2.0)   | 4 (1.5)   | - (0.0)    | 1 (2.3)    | 2 (1.6)     | 32 (1.7)    | 1 (11.1)   | - (0.0)    | 1 (7.1)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 2 (2.2)   | 7 (1.6)    | 19 (1.9)     | 5 (1.8)   | - (0.0)    | 1 (2.2)    | 2 (1.6)     | 34 (1.7)    |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Elevation of aspartate transaminase levels, 3x higher                                                              |  | 1 (0.2)                                                                                                                      | 6 (0.6)    | 1 (0.4)   | 1 (0.8)    | - (0.0)    | 2 (1.6)     | 11 (0.6)    | - (0.0)    | - (0.0)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | - (0.0)   | 1 (0.2)    | 6 (0.6)      | 1 (0.4)   | 1 (0.7)    | - (0.0)    | 2 (1.6)     | 11 (0.5)    |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |
| Elevation of bilirubin level, 1.5x higher                                                                          |  | 2 (0.5)                                                                                                                      | 3 (0.3)    | 3 (1.1)   | 2 (1.5)    | - (0.0)    | - (0.0)     | 10 (0.5)    | - (0.0)    | 1 (1.7)    | - (0.0)  | - (0.0)    | - (0.0)                                                                                                                | - (0.0)     | 1 (1.1)   | 2 (0.5)    | 4 (0.4)      | 3 (1.1)   | 2 (1.5)    | - (0.0)    | - (0.0)     | 11 (0.5)    |          |                                                                                                                                                                          |  |  |  |  |  |  |  |  |  |  |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all serious liver injury cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective period and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

Table 3. Interstitial Lung Disease Counts, By Cohort, HealthCore Integrated Research Database (HIRD)<sup>1,2,3</sup>

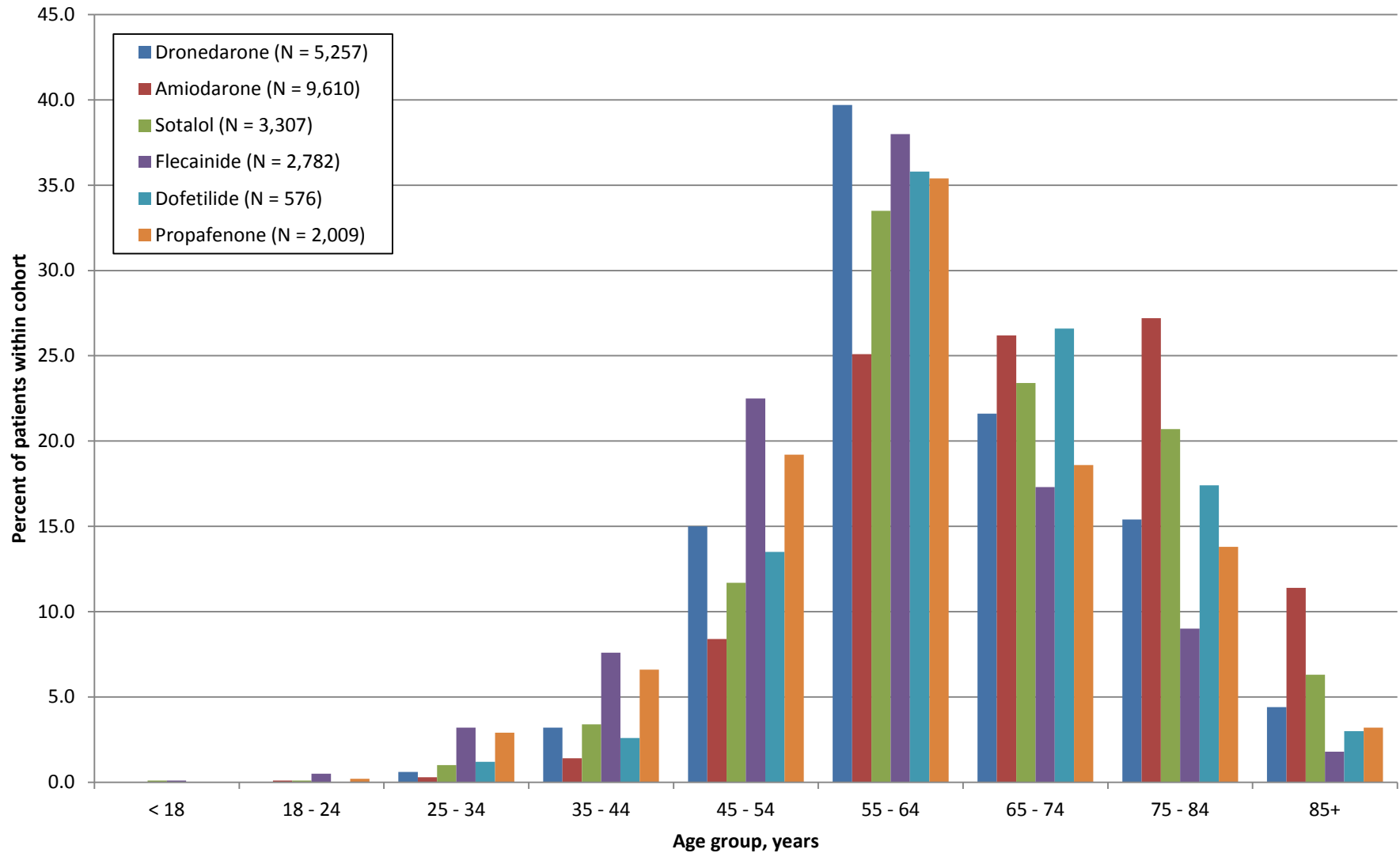
| Events                                                           | Interstitial Lung Disease Occurrences Among Patients Identified During Retrospective Period <sup>1</sup><br>(Jul 2009 – Dec 2011) |            |           |           |            |             |            | Interstitial Lung Disease Occurrences Among Patients Identified During Current Period<br>(Jan 2012 – Apr 2012) |            |          |           |            |             |           | Total Interstitial Lung Disease Occurrences Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 – Apr 2012)<br>(Retrospective + Current Period) |            |           |           |            |             |            |
|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|------------|-----------|-----------|------------|-------------|------------|----------------------------------------------------------------------------------------------------------------|------------|----------|-----------|------------|-------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|-----------|------------|-------------|------------|
|                                                                  | Dronedarone                                                                                                                       | Amiodarone | Sotalol   | Flexinide | Dofetilide | Propafenone | Total      | Dronedarone                                                                                                    | Amiodarone | Sotalol  | Flexinide | Dofetilide | Propafenone | Total     | Dronedarone                                                                                                                                                                   | Amiodarone | Sotalol   | Flexinide | Dofetilide | Propafenone | Total      |
|                                                                  | Patients<br>N (%)                                                                                                                 | N (%)      | N (%)     | N (%)     | N (%)      | N (%)       | N (%)      | N (%)                                                                                                          | N (%)      | N (%)    | N (%)     | N (%)      | N (%)       | N (%)     | N (%)                                                                                                                                                                         | N (%)      | N (%)     | N (%)     | N (%)      | N (%)       | N (%)      |
| Total <sup>5</sup>                                               | 172 (3.5)                                                                                                                         | 336 (4.1)  | 91 (3.2)  | 39 (1.7)  | 11 (2.3)   | 42 (2.4)    | 691 (3.4)  | 1 (0.3)                                                                                                        | 18 (1.2)   | 6 (1.3)  | 2 (0.5)   | - (0.0)    | 2 (0.7)     | 29 (0.9)  | 173 (3.3)                                                                                                                                                                     | 354 (3.7)  | 97 (2.9)  | 41 (1.5)  | 11 (1.9)   | 44 (2.2)    | 720 (3.1)  |
| Interstitial Lung Disease <sup>6</sup>                           |                                                                                                                                   |            |           |           |            |             |            |                                                                                                                |            |          |           |            |             |           |                                                                                                                                                                               |            |           |           |            |             |            |
| ICD-9-CM Diagnoses                                               |                                                                                                                                   |            |           |           |            |             |            |                                                                                                                |            |          |           |            |             |           |                                                                                                                                                                               |            |           |           |            |             |            |
| 495.9x Unspecified allergic alveolitis and pneumonitis           | - (0.0)                                                                                                                           | 6 (1.8)    | 3 (3.3)   | 2 (5.1)   | - (0.0)    | 2 (4.8)     | 13 (1.9)   | - (0.0)                                                                                                        | 1 (5.0)    | - (0.0)  | - (0.0)   | - (0.0)    | - (0.0)     | 1 (3.4)   | - (0.0)                                                                                                                                                                       | 7 (2.0)    | 3 (3.1)   | 2 (4.9)   | - (0.0)    | 2 (4.5)     | 14 (1.9)   |
| 515.xx Postinflammatory pulmonary fibrosis                       | 143 (83.1)                                                                                                                        | 262 (78.0) | 72 (79.1) | 30 (76.9) | 9 (81.8)   | 34 (81.0)   | 550 (79.4) | 1 (100.0)                                                                                                      | 14 (77.8)  | 5 (83.3) | 2 (100.0) | - (0.0)    | 2 (100.0)   | 24 (82.8) | 144 (83.2)                                                                                                                                                                    | 276 (78.0) | 77 (79.4) | 32 (78.0) | 9 (81.8)   | 36 (81.8)   | 574 (79.7) |
| 516.3x Idiopathic fibrosing alveolitis                           | 16 (9.3)                                                                                                                          | 30 (8.9)   | 9 (9.9)   | 3 (7.7)   | 3 (27.3)   | 6 (14.3)    | 67 (9.7)   | - (0.0)                                                                                                        | 2 (11.1)   | - (0.0)  | - (0.0)   | - (0.0)    | 1 (50.0)    | 3 (10.3)  | 16 (9.2)                                                                                                                                                                      | 32 (9.0)   | 9 (9.3)   | 3 (7.3)   | 3 (27.3)   | 7 (15.9)    | 70 (9.7)   |
| 516.8x Other specified alveolar and parietoalveolar pneumonopath | 5 (2.9)                                                                                                                           | 16 (4.8)   | 5 (5.5)   | 2 (5.1)   | - (0.0)    | 2 (4.8)     | 30 (4.3)   | - (0.0)                                                                                                        | - (0.0)    | - (0.0)  | - (0.0)   | - (0.0)    | - (0.0)     | - (0.0)   | 5 (2.9)                                                                                                                                                                       | 16 (4.5)   | 5 (5.2)   | 2 (4.9)   | - (0.0)    | 2 (4.5)     | 30 (4.2)   |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy    | 12 (7.0)                                                                                                                          | 28 (8.3)   | 7 (7.7)   | 2 (5.1)   | - (0.0)    | - (0.0)     | 49 (7.1)   | - (0.0)                                                                                                        | 1 (5.6)    | 1 (16.7) | - (0.0)   | - (0.0)    | - (0.0)     | 2 (6.9)   | 12 (6.9)                                                                                                                                                                      | 29 (8.2)   | 8 (8.2)   | 2 (4.9)   | - (0.0)    | - (0.0)     | 51 (7.1)   |

1. This Table will be completed each quarter during the prospective count.
2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all interstitial lung disease cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.
3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.
4. Eligibility criteria were reassessed for patients identified during the retrospective period and only those still eligible are included.
5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.
6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

| <b>Patients</b>                                                                     | <b>Dronedarone<br/>5257<br/>N (%)</b> | <b>Amlodarone<br/>9610<br/>N (%)</b> | <b>Sotalol<br/>3307<br/>N (%)</b> | <b>Flecainide<br/>2782<br/>N (%)</b> | <b>Dofetilide<br/>576<br/>N (%)</b> | <b>Propafenone<br/>2009<br/>N (%)</b> | <b>Total<br/>23541<br/>N (%)</b> |
|-------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-----------------------------------|--------------------------------------|-------------------------------------|---------------------------------------|----------------------------------|
| <b>Total patients identified through end of current period, Jul 2009 - Apr 2012</b> | <b>5,257 (22.3)</b>                   | <b>9,610 (40.8)</b>                  | <b>3,307 (14.0)</b>               | <b>2,782 (11.8)</b>                  | <b>576 (2.4)</b>                    | <b>2,009 (8.5)</b>                    | <b>23,541</b>                    |
| <b>Age group, years</b>                                                             |                                       |                                      |                                   |                                      |                                     |                                       |                                  |
| < 18                                                                                | 1 (0.0)                               | 1 (0.0)                              | 2 (0.1)                           | 3 (0.1)                              | - (0.0)                             | - (0.0)                               | 7 (0.0)                          |
| 18 - 24                                                                             | 2 (0.0)                               | 7 (0.1)                              | 2 (0.1)                           | 15 (0.5)                             | - (0.0)                             | 5 (0.2)                               | 31 (0.1)                         |
| 25 - 34                                                                             | 34 (0.6)                              | 31 (0.3)                             | 32 (1.0)                          | 88 (3.2)                             | 7 (1.2)                             | 58 (2.9)                              | 250 (1.1)                        |
| 35 - 44                                                                             | 167 (3.2)                             | 130 (1.4)                            | 111 (3.4)                         | 212 (7.6)                            | 15 (2.6)                            | 132 (6.6)                             | 767 (3.3)                        |
| 45 - 54                                                                             | 788 (15.0)                            | 805 (8.4)                            | 386 (11.7)                        | 627 (22.5)                           | 78 (13.5)                           | 386 (19.2)                            | 3,070 (13.0)                     |
| 55 - 64                                                                             | 2,086 (39.7)                          | 2,411 (25.1)                         | 1,108 (33.5)                      | 1,056 (38.0)                         | 206 (35.8)                          | 711 (35.4)                            | 7,578 (32.2)                     |
| 65 - 74                                                                             | 1,138 (21.6)                          | 2,520 (26.2)                         | 773 (23.4)                        | 481 (17.3)                           | 153 (26.6)                          | 374 (18.6)                            | 5,439 (23.1)                     |
| 75 - 84                                                                             | 808 (15.4)                            | 2,612 (27.2)                         | 684 (20.7)                        | 249 (9.0)                            | 100 (17.4)                          | 278 (13.8)                            | 4,731 (20.1)                     |
| 85+                                                                                 | 233 (4.4)                             | 1,093 (11.4)                         | 209 (6.3)                         | 51 (1.8)                             | 17 (3.0)                            | 65 (3.2)                              | 1,668 (7.1)                      |
| <b>Age group, female, years</b>                                                     | <b>1,807 (34.4)</b>                   | <b>3,391 (35.3)</b>                  | <b>1,287 (38.9)</b>               | <b>1,087 (39.1)</b>                  | <b>180 (31.3)</b>                   | <b>744 (37.0)</b>                     | <b>8,496 (36.1)</b>              |
| < 18, female                                                                        | - (0.0)                               | 1 (0.0)                              | 1 (0.1)                           | - (0.0)                              | - (0.0)                             | - (0.0)                               | 2 (0.0)                          |
| 18 - 24, female                                                                     | - (0.0)                               | 1 (0.0)                              | - (0.0)                           | 3 (0.3)                              | - (0.0)                             | 1 (0.1)                               | 5 (0.1)                          |
| 25 - 34, female                                                                     | 8 (0.4)                               | 7 (0.2)                              | 8 (0.6)                           | 21 (1.9)                             | 2 (1.1)                             | 11 (1.5)                              | 57 (0.7)                         |
| 35 - 44, female                                                                     | 32 (1.8)                              | 26 (0.8)                             | 21 (1.6)                          | 58 (5.3)                             | 5 (2.8)                             | 28 (3.8)                              | 170 (2.0)                        |
| 45 - 54, female                                                                     | 161 (8.9)                             | 165 (4.9)                            | 101 (7.8)                         | 192 (17.7)                           | 13 (7.2)                            | 89 (12.0)                             | 721 (8.5)                        |
| 55 - 64, female                                                                     | 644 (35.6)                            | 579 (17.1)                           | 341 (26.5)                        | 387 (35.6)                           | 58 (32.2)                           | 248 (33.3)                            | 2,257 (26.6)                     |
| 65 - 74, female                                                                     | 425 (23.5)                            | 813 (24.0)                           | 312 (24.2)                        | 228 (21.0)                           | 44 (24.4)                           | 168 (22.6)                            | 1,990 (23.4)                     |
| 75 - 84, female                                                                     | 388 (21.5)                            | 1,146 (33.8)                         | 362 (28.1)                        | 158 (14.5)                           | 48 (26.7)                           | 155 (20.8)                            | 2,257 (26.6)                     |
| 85+, female                                                                         | 149 (8.2)                             | 653 (19.3)                           | 141 (11.0)                        | 40 (3.7)                             | 10 (5.6)                            | 44 (5.9)                              | 1,037 (12.2)                     |
| <b>Age group, male, years</b>                                                       | <b>3,450 (65.6)</b>                   | <b>6,219 (64.7)</b>                  | <b>2,020 (61.1)</b>               | <b>1,695 (60.9)</b>                  | <b>396 (68.8)</b>                   | <b>1,265 (63.0)</b>                   | <b>15,045 (63.9)</b>             |
| < 18, male                                                                          | 1 (0.0)                               | - (0.0)                              | 1 (0.0)                           | 3 (0.2)                              | - (0.0)                             | - (0.0)                               | 5 (0.0)                          |
| 18 - 24, male                                                                       | 2 (0.1)                               | 6 (0.1)                              | 2 (0.1)                           | 12 (0.7)                             | - (0.0)                             | 4 (0.3)                               | 26 (0.2)                         |
| 25 - 34, male                                                                       | 26 (0.8)                              | 24 (0.4)                             | 24 (1.2)                          | 67 (4.0)                             | 5 (1.3)                             | 47 (3.7)                              | 193 (1.3)                        |
| 35 - 44, male                                                                       | 135 (3.9)                             | 104 (1.7)                            | 90 (4.5)                          | 154 (9.1)                            | 10 (2.5)                            | 104 (8.2)                             | 597 (4.0)                        |
| 45 - 54, male                                                                       | 627 (18.2)                            | 640 (10.3)                           | 285 (14.1)                        | 435 (25.7)                           | 65 (16.4)                           | 297 (23.5)                            | 2,349 (15.6)                     |
| 55 - 64, male                                                                       | 1,442 (41.8)                          | 1,832 (29.5)                         | 767 (38.0)                        | 669 (39.5)                           | 148 (37.4)                          | 463 (36.6)                            | 5,321 (35.4)                     |
| 65 - 74, male                                                                       | 713 (20.7)                            | 1,707 (27.4)                         | 461 (22.8)                        | 253 (14.9)                           | 109 (27.5)                          | 206 (16.3)                            | 3,449 (22.9)                     |
| 75 - 84, male                                                                       | 420 (12.2)                            | 1,466 (23.6)                         | 322 (15.9)                        | 91 (5.4)                             | 52 (13.1)                           | 123 (9.7)                             | 2,474 (16.4)                     |
| 85+, male                                                                           | 84 (2.4)                              | 440 (7.1)                            | 68 (3.4)                          | 11 (0.6)                             | 7 (1.8)                             | 21 (1.7)                              | 631 (4.2)                        |

1. This Table will be completed each quarter during the prospective count.  
2. Only the index study drug will be counted, therefore a patient is only counted once.  
3. Eligibility criteria were reassessed for patients identified during the retrospective period and only those still eligible are included.

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Apr 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)**





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Table 1. New Index Dronedaronone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Table 4. Age Distribution of Index Users, By Gender and Cohort, Through End of Current Period (Jul 2009 - Jul 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

Figure 1. Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Jul 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

| Table 1. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD <sup>SM1,2,3</sup> )                      |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------|------------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|--------|--------|
| Patients                                                                                                                                                           | Dronedarone |        | Amiodarone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total  |        |
|                                                                                                                                                                    | N           | (%)    | N          | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N      | (%)    |
| Total patients identified through end of current period, Jul 2009 - Jul 2012 <sup>4</sup>                                                                          | 5,099       | (21.6) | 9,472      | (40.1) | 3,521   | (14.9) | 2,858      | (12.1) | 572        | (2.4)  | 2,114       | (8.9)  | 23,636 |        |
| Patients identified prior to current period, Jul 2009 - Apr 2012 <sup>4</sup>                                                                                      | 4,865       | (95.4) | 8,445      | (89.2) | 3,223   | (91.5) | 2,584      | (90.4) | 500        | (87.4) | 1,934       | (91.5) | 21,551 | (91.2) |
| New index patients identified during current period, May 2012 - Jul 2012                                                                                           | 234         | (4.6)  | 1,027      | (10.8) | 298     | (8.5)  | 274        | (9.6)  | 72         | (12.6) | 180         | (8.5)  | 2,085  | (8.8)  |
| 1. This Table will be completed each quarter during the prospective count.                                                                                         |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                            |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.         |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |             |        |            |        |         |        |            |        |            |        |             |        |        |        |

**Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD)**<sup>SM 1,2,3</sup>

| Events                                                                   | Patients | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Jul 2012) |              |              |               |            |              |            |              |            |              | Total SLI Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(May 2012 - Jul 2012) |              | Cumulative Total SLI Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Jul 2012) |              |
|--------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|---------------|------------|--------------|------------|--------------|------------|--------------|-----------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                          |          | Dronedaron                                                                                                                            |              | Amiodarone   |               | Sotalol    |              | Flecainide |              | Dofetilide |              | Propafenone                                                                                               |              | Total                                                                                                                                |              |
|                                                                          |          | 5,099                                                                                                                                 | 9,472        | 3,521        | 2,858         | 572        | 2,114        | 2,085      | 23,636       | Total      |              | Total                                                                                                     |              | Total                                                                                                                                |              |
|                                                                          |          | N (%)                                                                                                                                 | N (%)        | N (%)        | N (%)         | N (%)      | N (%)        | N (%)      | N (%)        | N (%)      | N (%)        | N (%)                                                                                                     | N (%)        | N (%)                                                                                                                                | N (%)        |
| <b>Total<sup>5</sup></b>                                                 |          | <b>409</b>                                                                                                                            | <b>(8.0)</b> | <b>1,003</b> | <b>(10.6)</b> | <b>305</b> | <b>(8.7)</b> | <b>148</b> | <b>(5.2)</b> | <b>51</b>  | <b>(8.9)</b> | <b>146</b>                                                                                                | <b>(6.9)</b> | <b>45</b>                                                                                                                            | <b>(2.2)</b> |
| <b>Serious Liver Injury<sup>6</sup></b>                                  |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| <u>ICD-9-CM Diagnoses</u>                                                |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| 570.xx Acute and subacute necrosis of liver                              |          | 10                                                                                                                                    | (2.4)        | 38           | (3.8)         | 9          | (3.0)        | 5          | (3.4)        | 2          | (3.9)        | 1                                                                                                         | (0.7)        | -                                                                                                                                    | (0.0)        |
| 571.5x Cirrhosis of liver without mention of alcohol                     |          | 12                                                                                                                                    | (2.9)        | 38           | (3.8)         | 12         | (3.9)        | 7          | (4.7)        | 4          | (7.8)        | 5                                                                                                         | (3.4)        | 3                                                                                                                                    | (6.7)        |
| 572.2x Hepatic coma                                                      |          | 2                                                                                                                                     | (0.5)        | 8            | (0.8)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | 3                                                                                                         | (2.1)        | -                                                                                                                                    | (0.0)        |
| 572.4x Hepatorenal syndrome                                              |          | 1                                                                                                                                     | (0.2)        | 3            | (0.3)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.xx Other disorders of liver                                          |          | 117                                                                                                                                   | (28.6)       | 267          | (26.6)        | 90         | (29.5)       | 53         | (35.8)       | 15         | (29.4)       | 53                                                                                                        | (36.3)       | 8                                                                                                                                    | (17.8)       |
| 573.0x Chronic passive congestion of liver                               |          | 2                                                                                                                                     | (0.5)        | 16           | (1.6)         | 2          | (0.7)        | 1          | (0.7)        | 1          | (2.0)        | 1                                                                                                         | (0.7)        | -                                                                                                                                    | (0.0)        |
| 573.3x Hepatitis, unspecified                                            |          | 20                                                                                                                                    | (4.9)        | 51           | (5.1)         | 15         | (4.9)        | 9          | (6.1)        | 1          | (2.0)        | 7                                                                                                         | (4.8)        | 1                                                                                                                                    | (2.2)        |
| 573.4x Hepatic infarction                                                |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.8x Other specified disorders of liver                                |          | 61                                                                                                                                    | (14.9)       | 137          | (13.7)        | 44         | (14.4)       | 37         | (25.0)       | 6          | (11.8)       | 32                                                                                                        | (21.9)       | 5                                                                                                                                    | (11.1)       |
| 573.9x Unspecified disorder of liver                                     |          | 36                                                                                                                                    | (8.8)        | 69           | (6.9)         | 31         | (10.2)       | 7          | (4.7)        | 9          | (17.6)       | 13                                                                                                        | (8.9)        | 2                                                                                                                                    | (4.4)        |
| 782.4x Jaundice, unspecified                                             |          | 8                                                                                                                                     | (2.0)        | 36           | (3.6)         | 9          | (3.0)        | 6          | (4.1)        | 2          | (3.9)        | 7                                                                                                         | (4.8)        | 1                                                                                                                                    | (2.2)        |
| 789.1x Hepatomegaly                                                      |          | 24                                                                                                                                    | (5.9)        | 31           | (3.1)         | 6          | (2.0)        | 6          | (4.1)        | 1          | (2.0)        | 4                                                                                                         | (2.7)        | 1                                                                                                                                    | (2.2)        |
| 789.5x Ascites                                                           |          | 34                                                                                                                                    | (8.3)        | 192          | (19.1)        | 31         | (10.2)       | 10         | (6.8)        | 7          | (13.7)       | 11                                                                                                        | (7.5)        | 8                                                                                                                                    | (17.8)       |
| 790.4x Nonspecific elevation of levels of transaminase or LDH            |          | 75                                                                                                                                    | (18.3)       | 123          | (12.3)        | 38         | (12.5)       | 20         | (13.5)       | 6          | (11.8)       | 23                                                                                                        | (15.8)       | 9                                                                                                                                    | (20.0)       |
| 790.5x Other or nonspecified abnormal serum levels                       |          | 72                                                                                                                                    | (17.6)       | 165          | (16.5)        | 74         | (24.3)       | 18         | (12.2)       | 9          | (17.6)       | 17                                                                                                        | (11.6)       | 11                                                                                                                                   | (24.4)       |
| 791.4x Biliruria                                                         |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | 1          | (0.7)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 794.8x Nonspecific abnormal results of liver function test               |          | 66                                                                                                                                    | (16.1)       | 117          | (11.7)        | 43         | (14.1)       | 21         | (14.2)       | 8          | (15.7)       | 20                                                                                                        | (13.7)       | 3                                                                                                                                    | (6.7)        |
| <u>ICD-9-CM Procedures</u>                                               |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                     |          | 1                                                                                                                                     | (0.2)        | 5            | (0.5)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.12 Open biopsy of liver                                               |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.13 Transjugular liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.14 Laparoscopic liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | 2            | (0.2)         | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.5x Liver transplant                                                   |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.51 Auxiliary liver transplant                                         |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.59 Other transplant of liver                                          |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.91 Percutaneous aspiration of liver                                   |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>CPT Procedures</u>                                                    |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| CPT 47000 Biopsy of liver, needle; percutaneous                          |          | 1                                                                                                                                     | (0.2)        | 6            | (0.6)         | 1          | (0.3)        | 1          | (0.7)        | 1          | (2.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47100 Biopsy of liver, wedge                                         |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | 2                                                                                                         | (1.4)        | -                                                                                                                                    | (0.0)        |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole        |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole       |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78205 Liver imaging (SPECT)                                          |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | 1          | (0.7)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78206 Liver imaging (SPECT); with vascular flow                      |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>Laboratory Test Values</u>                                            |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| Elevation of alanine transaminase levels, 3x higher                      |          | 7                                                                                                                                     | (1.7)        | 19           | (1.9)         | 6          | (2.0)        | 1          | (0.7)        | 1          | (2.0)        | 3                                                                                                         | (2.1)        | 2                                                                                                                                    | (4.4)        |
| Elevation of aspartate transaminase levels, 3x higher                    |          | 2                                                                                                                                     | (0.5)        | 7            | (0.7)         | 2          | (0.7)        | 2          | (1.4)        | -          | (0.0)        | 2                                                                                                         | (1.4)        | 1                                                                                                                                    | (2.2)        |
| Elevation of bilirubin level, 1.5x higher                                |          | 2                                                                                                                                     | (0.5)        | 4            | (0.4)         | 3          | (1.0)        | 3          | (2.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLI cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD)** <sup>SM 1,2,3</sup>

| Events                                                              | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Jul 2012) |                   |                  |                   |                   |                    | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(May 2012 - Jul 2012) |  | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Jul 2012) |  |
|---------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|-------------------|-------------------|--------------------|-----------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                     |          | <u>Dronedarone</u>                                                                                                                    | <u>Amiodarone</u> | <u>Sotalol</u>   | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u>                                                                                              |  | <u>Total</u>                                                                                                                         |  |
|                                                                     |          | 5,099<br>N (%)                                                                                                                        | 9,472<br>N (%)    | 3,521<br>N (%)   | 2,858<br>N (%)    | 572<br>N (%)      | 2,114<br>N (%)     | 2,085<br>N (%)                                                                                            |  | 23,636<br>N (%)                                                                                                                      |  |
| <b>Total<sup>5</sup></b>                                            |          | <b>168 (3.3)</b>                                                                                                                      | <b>344 (3.6)</b>  | <b>112 (3.2)</b> | <b>44 (1.5)</b>   | <b>19 (3.3)</b>   | <b>42 (2.0)</b>    | <b>14 (0.7)</b>                                                                                           |  | <b>729 (3.1)</b>                                                                                                                     |  |
| Interstitial Lung Disease <sup>6</sup>                              |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |  |                                                                                                                                      |  |
| ICD-9-CM Diagnoses                                                  |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |  |                                                                                                                                      |  |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |          | - (0.0)                                                                                                                               | 6 (1.7)           | 3 (2.7)          | 2 (4.5)           | - (0.0)           | 1 (2.4)            | - (0.0)                                                                                                   |  | 12 (1.6)                                                                                                                             |  |
| 515.xx Postinflammatory pulmonary fibrosis                          |          | 143 (85.1)                                                                                                                            | 267 (77.6)        | 91 (81.3)        | 33 (75.0)         | 16 (84.2)         | 37 (88.1)          | 10 (71.4)                                                                                                 |  | 587 (80.5)                                                                                                                           |  |
| 516.3x Idiopathic fibrosing alveolitis                              |          | 14 (8.3)                                                                                                                              | 31 (9.0)          | 10 (8.9)         | 4 (9.1)           | 3 (15.8)          | 4 (9.5)            | 2 (14.3)                                                                                                  |  | 66 (9.1)                                                                                                                             |  |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |          | 5 (3.0)                                                                                                                               | 20 (5.8)          | 4 (3.6)          | 2 (4.5)           | - (0.0)           | 1 (2.4)            | 2 (14.3)                                                                                                  |  | 32 (4.4)                                                                                                                             |  |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |          | 10 (6.0)                                                                                                                              | 26 (7.6)          | 8 (7.1)          | 3 (6.8)           | - (0.0)           | 1 (2.4)            | - (0.0)                                                                                                   |  | 48 (6.6)                                                                                                                             |  |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

Table 4. Age Distribution of Index Users, By Gender and Cohort, Through End of Current Period (Jul 2009 - Jul 2012), HealthCore Integrated Research Database (HIRD)<sup>SM1,2,3</sup>

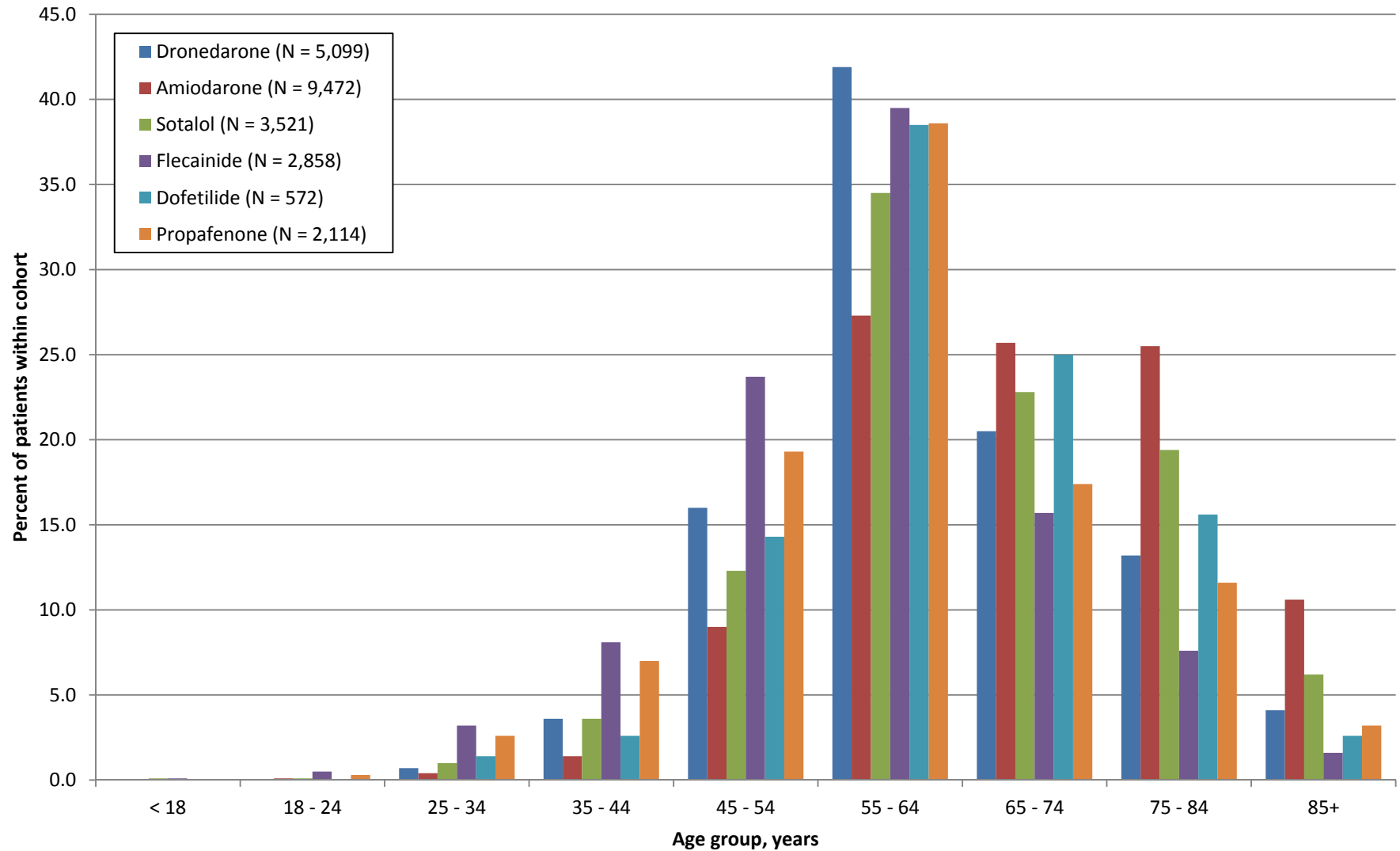
| Patients                                                                     | Dronedaronone<br>5,099 |        | Amiodarone<br>9,472 |        | Sotalol<br>3,521 |        | Flecainide<br>2,858 |        | Dofetilide<br>572 |        | Propafenone<br>2,114 |        | Total<br>23,636 |        |
|------------------------------------------------------------------------------|------------------------|--------|---------------------|--------|------------------|--------|---------------------|--------|-------------------|--------|----------------------|--------|-----------------|--------|
|                                                                              | N                      | (%)    | N                   | (%)    | N                | (%)    | N                   | (%)    | N                 | (%)    | N                    | (%)    | N               | (%)    |
| Total patients identified through end of current period, Jul 2009 - Jul 2012 | 5,099                  | (21.6) | 9,472               | (40.1) | 3,521            | (14.9) | 2,858               | (12.1) | 572               | (2.4)  | 2,114                | (8.9)  | 23,636          |        |
| Age group, years                                                             |                        |        |                     |        |                  |        |                     |        |                   |        |                      |        |                 |        |
| < 18                                                                         | 1                      | (0.0)  | 2                   | (0.0)  | 3                | (0.1)  | 3                   | (0.1)  | -                 | (0.0)  | -                    | (0.0)  | 9               | (0.0)  |
| 18 - 24                                                                      | 2                      | (0.0)  | 7                   | (0.1)  | 3                | (0.1)  | 15                  | (0.5)  | -                 | (0.0)  | 7                    | (0.3)  | 34              | (0.1)  |
| 25 - 34                                                                      | 36                     | (0.7)  | 36                  | (0.4)  | 34               | (1.0)  | 91                  | (3.2)  | 8                 | (1.4)  | 55                   | (2.6)  | 260             | (1.1)  |
| 35 - 44                                                                      | 182                    | (3.6)  | 135                 | (1.4)  | 127              | (3.6)  | 232                 | (8.1)  | 15                | (2.6)  | 147                  | (7.0)  | 838             | (3.5)  |
| 45 - 54                                                                      | 814                    | (16.0) | 849                 | (9.0)  | 433              | (12.3) | 677                 | (23.7) | 82                | (14.3) | 409                  | (19.3) | 3,264           | (13.8) |
| 55 - 64                                                                      | 2,136                  | (41.9) | 2,585               | (27.3) | 1,216            | (34.5) | 1,129               | (39.5) | 220               | (38.5) | 816                  | (38.6) | 8,102           | (34.3) |
| 65 - 74                                                                      | 1,045                  | (20.5) | 2,436               | (25.7) | 803              | (22.8) | 449                 | (15.7) | 143               | (25.0) | 367                  | (17.4) | 5,243           | (22.2) |
| 75 - 84                                                                      | 675                    | (13.2) | 2,414               | (25.5) | 684              | (19.4) | 216                 | (7.6)  | 89                | (15.6) | 245                  | (11.6) | 4,323           | (18.3) |
| 85+                                                                          | 208                    | (4.1)  | 1,008               | (10.6) | 218              | (6.2)  | 46                  | (1.6)  | 15                | (2.6)  | 68                   | (3.2)  | 1,563           | (6.6)  |
| Age group, female, years                                                     |                        |        |                     |        |                  |        |                     |        |                   |        |                      |        |                 |        |
| < 18, female                                                                 | -                      | (0.0)  | 2                   | (0.1)  | 2                | (0.1)  | -                   | (0.0)  | -                 | (0.0)  | -                    | (0.0)  | 4               | (0.0)  |
| 18 - 24, female                                                              | -                      | (0.0)  | 1                   | (0.0)  | 1                | (0.1)  | 3                   | (0.3)  | -                 | (0.0)  | 2                    | (0.3)  | 7               | (0.1)  |
| 25 - 34, female                                                              | 9                      | (0.5)  | 9                   | (0.3)  | 6                | (0.4)  | 24                  | (2.1)  | 2                 | (1.1)  | 11                   | (1.4)  | 61              | (0.7)  |
| 35 - 44, female                                                              | 37                     | (2.1)  | 27                  | (0.8)  | 25               | (1.9)  | 61                  | (5.4)  | 3                 | (1.7)  | 29                   | (3.8)  | 182             | (2.2)  |
| 45 - 54, female                                                              | 168                    | (9.7)  | 168                 | (5.1)  | 112              | (8.3)  | 211                 | (18.6) | 12                | (6.8)  | 94                   | (12.2) | 765             | (9.1)  |
| 55 - 64, female                                                              | 659                    | (38.0) | 615                 | (18.8) | 372              | (27.6) | 425                 | (37.5) | 62                | (35.2) | 293                  | (38.0) | 2,426           | (28.8) |
| 65 - 74, female                                                              | 395                    | (22.8) | 773                 | (23.6) | 300              | (22.3) | 230                 | (20.3) | 46                | (26.1) | 156                  | (20.2) | 1,900           | (22.5) |
| 75 - 84, female                                                              | 328                    | (18.9) | 1,074               | (32.8) | 381              | (28.3) | 142                 | (12.5) | 41                | (23.3) | 139                  | (18.0) | 2,105           | (24.9) |
| 85+, female                                                                  | 138                    | (8.0)  | 607                 | (18.5) | 147              | (10.9) | 38                  | (3.4)  | 10                | (5.7)  | 48                   | (6.2)  | 988             | (11.7) |
| Age group, male, years                                                       |                        |        |                     |        |                  |        |                     |        |                   |        |                      |        |                 |        |
| < 18, male                                                                   | 1                      | (0.0)  | -                   | (0.0)  | 1                | (0.0)  | 3                   | (0.2)  | -                 | (0.0)  | -                    | (0.0)  | 5               | (0.0)  |
| 18 - 24, male                                                                | 2                      | (0.1)  | 6                   | (0.1)  | 2                | (0.1)  | 12                  | (0.7)  | -                 | (0.0)  | 5                    | (0.4)  | 27              | (0.2)  |
| 25 - 34, male                                                                | 27                     | (0.8)  | 27                  | (0.4)  | 28               | (1.3)  | 67                  | (3.9)  | 6                 | (1.5)  | 44                   | (3.3)  | 199             | (1.3)  |
| 35 - 44, male                                                                | 145                    | (4.3)  | 108                 | (1.7)  | 102              | (4.7)  | 171                 | (9.9)  | 12                | (3.0)  | 118                  | (8.8)  | 656             | (4.3)  |
| 45 - 54, male                                                                | 646                    | (19.2) | 681                 | (11.0) | 321              | (14.8) | 466                 | (27.0) | 70                | (17.7) | 315                  | (23.5) | 2,499           | (16.4) |
| 55 - 64, male                                                                | 1,477                  | (43.9) | 1,970               | (31.8) | 844              | (38.8) | 704                 | (40.8) | 158               | (39.9) | 523                  | (39.0) | 5,676           | (37.3) |
| 65 - 74, male                                                                | 650                    | (19.3) | 1,663               | (26.8) | 503              | (23.1) | 219                 | (12.7) | 97                | (24.5) | 211                  | (15.7) | 3,343           | (22.0) |
| 75 - 84, male                                                                | 347                    | (10.3) | 1,340               | (21.6) | 303              | (13.9) | 74                  | (4.3)  | 48                | (12.1) | 106                  | (7.9)  | 2,218           | (14.6) |
| 85+, male                                                                    | 70                     | (2.1)  | 401                 | (6.5)  | 71               | (3.3)  | 8                   | (0.5)  | 5                 | (1.3)  | 20                   | (1.5)  | 575             | (3.8)  |

1. This Table will be completed each quarter during the prospective count.

2. Only the index study drug will be counted, therefore a patient is only counted once.

3. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Jul 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)**



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| Table 1. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD <sup>SM</sup> 1,2,3)                      |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------|------------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|--------|--------|
| Patients                                                                                                                                                           | Dronedarone |        | Amiodarone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total  |        |
|                                                                                                                                                                    | N           | (%)    | N          | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N      | (%)    |
| Total patients identified through end of current period, Jul 2009 - Nov 2012 <sup>4</sup>                                                                          | 5,027       | (19.8) | 10,312     | (40.6) | 3,899   | (15.3) | 3,230      | (12.7) | 631        | (2.5)  | 2,314       | (9.1)  | 25,413 |        |
| Patients identified prior to current period, Jul 2009 - Jul 2012 <sup>4</sup>                                                                                      | 4,763       | (94.7) | 8,956      | (86.9) | 3,430   | (88.0) | 2,825      | (87.5) | 540        | (85.6) | 2,048       | (88.5) | 22,562 | (88.8) |
| New index patients identified during current period, Aug 2012 - Nov 2012                                                                                           | 264         | (5.3)  | 1,356      | (13.1) | 469     | (12.0) | 405        | (12.5) | 91         | (14.4) | 266         | (11.5) | 2,851  | (11.2) |
| 1. This Table will be completed each quarter during the prospective count.                                                                                         |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                            |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.         |             |        |            |        |         |        |            |        |            |        |             |        |        |        |
| 4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |             |        |            |        |         |        |            |        |            |        |             |        |        |        |



**Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM,1,2,3</sup>)**

| Events                                                                   |  | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2012) |        |           |        |         |        |            |        |            |        |             |        |       |        | Total SLI Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Aug 2012 - Nov 2012) |        | Cumulative Total SLI Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2012) |  |
|--------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------------------------|--------|-----------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|-------|--------|-----------------------------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                          |  | Dronedaron                                                                                                                            |        | Amiodaron |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total |        | Total                                                                                                     |        |                                                                                                                                      |  |
|                                                                          |  | 5,027                                                                                                                                 | 10,312 | 3,899     | 3,230  | 631     | 2,314  | 2,851      | 25,413 |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| Patients                                                                 |  | N                                                                                                                                     | (%)    | N         | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N     | (%)    | N                                                                                                         | (%)    |                                                                                                                                      |  |
| Total <sup>1</sup>                                                       |  | 427                                                                                                                                   | (8.5)  | 1,088     | (10.6) | 336     | (8.6)  | 177        | (5.5)  | 52         | (8.2)  | 164         | (7.1)  | 88    | (3.1)  | 2,244                                                                                                     | (8.8)  |                                                                                                                                      |  |
| Serious Liver Injury <sup>6</sup>                                        |  |                                                                                                                                       |        |           |        |         |        |            |        |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| ICD-9-CM Diagnoses                                                       |  |                                                                                                                                       |        |           |        |         |        |            |        |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| 570.xx Acute and subacute necrosis of liver                              |  | 12                                                                                                                                    | (2.8)  | 40        | (3.7)  | 9       | (2.7)  | 5          | (2.8)  | 2          | (3.8)  | 1           | (0.6)  | 2     | (2.3)  | 69                                                                                                        | (3.1)  |                                                                                                                                      |  |
| 571.5x Cirrhosis of liver without mention of alcohol                     |  | 12                                                                                                                                    | (2.8)  | 37        | (3.4)  | 15      | (4.5)  | 9          | (5.1)  | 3          | (5.8)  | 6           | (3.7)  | 7     | (8.0)  | 82                                                                                                        | (3.7)  |                                                                                                                                      |  |
| 572.2x Hepatic coma                                                      |  | 2                                                                                                                                     | (0.5)  | 6         | (0.6)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | 3           | (1.8)  | -     | (0.0)  | 12                                                                                                        | (0.5)  |                                                                                                                                      |  |
| 572.4x Hepatorenal syndrome                                              |  | 1                                                                                                                                     | (0.2)  | 3         | (0.3)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 4                                                                                                         | (0.2)  |                                                                                                                                      |  |
| 573.xx Other disorders of liver                                          |  | 120                                                                                                                                   | (28.1) | 283       | (26.0) | 101     | (30.1) | 61         | (34.5) | 15         | (28.8) | 57          | (34.8) | 20    | (22.7) | 637                                                                                                       | (28.4) |                                                                                                                                      |  |
| 573.0x Chronic passive congestion of liver                               |  | 2                                                                                                                                     | (0.5)  | 17        | (1.6)  | 3       | (0.9)  | 1          | (0.6)  | 1          | (1.9)  | 1           | (0.6)  | 2     | (2.3)  | 25                                                                                                        | (1.1)  |                                                                                                                                      |  |
| 573.3x Hepatitis, unspecified                                            |  | 18                                                                                                                                    | (4.2)  | 57        | (5.2)  | 20      | (6.0)  | 10         | (5.6)  | 2          | (3.8)  | 9           | (5.5)  | 5     | (5.7)  | 116                                                                                                       | (5.2)  |                                                                                                                                      |  |
| 573.4x Hepatic infarction                                                |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 573.8x Other specified disorders of liver                                |  | 68                                                                                                                                    | (15.9) | 144       | (13.2) | 48      | (14.3) | 40         | (22.6) | 6          | (11.5) | 35          | (21.3) | 9     | (10.2) | 341                                                                                                       | (15.2) |                                                                                                                                      |  |
| 573.9x Unspecified disorder of liver                                     |  | 34                                                                                                                                    | (8.0)  | 72        | (6.6)  | 33      | (9.8)  | 11         | (6.2)  | 8          | (15.4) | 13          | (7.9)  | 4     | (4.5)  | 171                                                                                                       | (7.6)  |                                                                                                                                      |  |
| 782.4x Jaundice, unspecified                                             |  | 8                                                                                                                                     | (1.9)  | 37        | (3.4)  | 8       | (2.4)  | 7          | (4.0)  | 1          | (1.9)  | 8           | (4.9)  | 2     | (2.3)  | 69                                                                                                        | (3.1)  |                                                                                                                                      |  |
| 789.1x Hepatomegaly                                                      |  | 23                                                                                                                                    | (5.4)  | 36        | (3.3)  | 7       | (2.1)  | 9          | (5.1)  | 2          | (3.8)  | 7           | (4.3)  | 3     | (3.4)  | 84                                                                                                        | (3.7)  |                                                                                                                                      |  |
| 789.5x Ascites                                                           |  | 39                                                                                                                                    | (9.1)  | 212       | (19.5) | 33      | (9.8)  | 11         | (6.2)  | 9          | (17.3) | 15          | (9.1)  | 14    | (15.9) | 319                                                                                                       | (14.2) |                                                                                                                                      |  |
| 790.4x Nonspecific elevation of levels of transaminase or LDH            |  | 76                                                                                                                                    | (17.8) | 136       | (12.5) | 40      | (11.9) | 27         | (15.3) | 5          | (9.6)  | 27          | (16.5) | 10    | (11.4) | 311                                                                                                       | (13.9) |                                                                                                                                      |  |
| 790.5x Other or nonspecific abnormal serum levels                        |  | 76                                                                                                                                    | (17.8) | 173       | (15.9) | 79      | (23.5) | 21         | (11.9) | 7          | (13.5) | 18          | (11.0) | 18    | (20.5) | 374                                                                                                       | (16.7) |                                                                                                                                      |  |
| 791.4x Biliuria                                                          |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | -       | (0.0)  | 1          | (0.6)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 2                                                                                                         | (0.1)  |                                                                                                                                      |  |
| 794.8x Nonspecific abnormal results of liver function test               |  | 65                                                                                                                                    | (15.2) | 127       | (11.7) | 45      | (13.4) | 24         | (13.6) | 9          | (17.3) | 20          | (12.2) | 11    | (12.5) | 290                                                                                                       | (12.9) |                                                                                                                                      |  |
| V42.7x Liver transplant status                                           |  | 5                                                                                                                                     | (1.2)  | 20        | (1.8)  | 5       | (1.5)  | 1          | (0.6)  | 2          | (3.8)  | -           | (0.0)  | 3     | (3.4)  | 33                                                                                                        | (1.5)  |                                                                                                                                      |  |
| ICD-9-CM Procedures                                                      |  |                                                                                                                                       |        |           |        |         |        |            |        |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                     |  | 1                                                                                                                                     | (0.2)  | 5         | (0.5)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 6                                                                                                         | (0.3)  |                                                                                                                                      |  |
| 50.12 Open biopsy of liver                                               |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 1                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 50.13 Transjugular liver biopsy                                          |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 1                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 50.14 Laparoscopic liver biopsy                                          |  | -                                                                                                                                     | (0.0)  | 2         | (0.2)  | 2       | (0.6)  | -          | (0.0)  | -          | (0.0)  | 1           | (0.6)  | -     | (0.0)  | 5                                                                                                         | (0.2)  |                                                                                                                                      |  |
| 50.5x Liver transplant                                                   |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 50.51 Auxiliary liver transplant                                         |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 50.59 Other transplant of liver                                          |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| 50.91 Percutaneous aspiration of liver                                   |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 2                                                                                                         | (0.1)  |                                                                                                                                      |  |
| CPT Procedures                                                           |  |                                                                                                                                       |        |           |        |         |        |            |        |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| CPT 47000 Biopsy of liver, needle; percutaneous                          |  | -                                                                                                                                     | (0.0)  | 3         | (0.3)  | 2       | (0.6)  | 2          | (1.1)  | 1          | (1.9)  | 1           | (0.6)  | 1     | (1.1)  | 9                                                                                                         | (0.4)  |                                                                                                                                      |  |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | 2       | (0.6)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 3                                                                                                         | (0.1)  |                                                                                                                                      |  |
| CPT 47100 Biopsy of liver, wedge                                         |  | -                                                                                                                                     | (0.0)  | 1         | (0.1)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | 2           | (1.2)  | -     | (0.0)  | 3                                                                                                         | (0.1)  |                                                                                                                                      |  |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole        |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole       |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| CPT 78205 Liver imaging (SPECT)                                          |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | 2          | (1.1)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 2                                                                                                         | (0.1)  |                                                                                                                                      |  |
| CPT 78206 Liver imaging (SPECT); with vascular flow                      |  | -                                                                                                                                     | (0.0)  | -         | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | -                                                                                                         | (0.0)  |                                                                                                                                      |  |
| Laboratory Test Values                                                   |  |                                                                                                                                       |        |           |        |         |        |            |        |            |        |             |        |       |        |                                                                                                           |        |                                                                                                                                      |  |
| Elevation of alanine transaminase levels, 3x higher                      |  | 11                                                                                                                                    | (2.6)  | 21        | (1.9)  | 6       | (1.8)  | 1          | (0.6)  | 1          | (1.9)  | 3           | (1.8)  | -     | (0.0)  | 43                                                                                                        | (1.9)  |                                                                                                                                      |  |
| Elevation of aspartate transaminase levels, 3x higher                    |  | 3                                                                                                                                     | (0.7)  | 9         | (0.8)  | 2       | (0.6)  | 2          | (1.1)  | -          | (0.0)  | 2           | (1.2)  | -     | (0.0)  | 18                                                                                                        | (0.8)  |                                                                                                                                      |  |
| Elevation of bilirubin level, 1.5x higher                                |  | 2                                                                                                                                     | (0.5)  | 4         | (0.4)  | 4       | (1.2)  | 3          | (1.7)  | -          | (0.0)  | -           | (0.0)  | -     | (0.0)  | 13                                                                                                        | (0.6)  |                                                                                                                                      |  |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLI cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM1,2,3</sup>)**

| Events                                                              | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2012) |                   |                  |                   |                   |                    | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Aug 2012 - Nov 2012) | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2012) |
|---------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|-------------------|-------------------|--------------------|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
|                                                                     |          | <u>Dronedarone</u>                                                                                                                    | <u>Amiodarone</u> | <u>Sotalol</u>   | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u>                                                                                              | <u>Total</u>                                                                                                                         |
|                                                                     |          | 5,027                                                                                                                                 | 10,312            | 3,899            | 3,230             | 631               | 2,314              | 2,851                                                                                                     | 25,413                                                                                                                               |
|                                                                     |          | N (%)                                                                                                                                 | N (%)             | N (%)            | N (%)             | N (%)             | N (%)              | N (%)                                                                                                     | N (%)                                                                                                                                |
| <b>Total<sup>5</sup></b>                                            |          | <b>159 (3.2)</b>                                                                                                                      | <b>376 (3.6)</b>  | <b>128 (3.3)</b> | <b>46 (1.4)</b>   | <b>20 (3.2)</b>   | <b>44 (1.9)</b>    | <b>26 (0.9)</b>                                                                                           | <b>773 (3.0)</b>                                                                                                                     |
| Interstitial Lung Disease <sup>6</sup>                              |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |                                                                                                                                      |
| ICD-9-CM Diagnoses                                                  |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |                                                                                                                                      |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |          | - (0.0)                                                                                                                               | 7 (1.9)           | 3 (2.3)          | 2 (4.3)           | - (0.0)           | 1 (2.3)            | - (0.0)                                                                                                   | 13 (1.7)                                                                                                                             |
| 515.xx Postinflammatory pulmonary fibrosis                          |          | 137 (86.2)                                                                                                                            | 291 (77.4)        | 105 (82.0)       | 33 (71.7)         | 17 (85.0)         | 38 (86.4)          | 20 (76.9)                                                                                                 | 621 (80.3)                                                                                                                           |
| 516.3x Idiopathic fibrosing alveolitis                              |          | 12 (7.5)                                                                                                                              | 39 (10.4)         | 12 (9.4)         | 5 (10.9)          | 3 (15.0)          | 4 (9.1)            | 4 (15.4)                                                                                                  | 75 (9.7)                                                                                                                             |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified   |          | 1 (0.6)                                                                                                                               | 2 (0.5)           | 1 (0.8)          | - (0.0)           | - (0.0)           | - (0.0)            | 1 (3.8)                                                                                                   | 4 (0.5)                                                                                                                              |
| 516.31 Idiopathic pulmonary fibrosis                                |          | 3 (1.9)                                                                                                                               | 12 (3.2)          | 2 (1.6)          | 1 (2.2)           | - (0.0)           | 1 (2.3)            | 1 (3.8)                                                                                                   | 19 (2.5)                                                                                                                             |
| 516.32 Idiopathic non-specific interstitial pneumonitis             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.33 Acute interstitial pneumonitis                               |          | - (0.0)                                                                                                                               | 2 (0.5)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | 1 (3.8)                                                                                                   | 2 (0.3)                                                                                                                              |
| 516.34 Respiratory bronchiolitis interstitial lung disease          |          | - (0.0)                                                                                                                               | 1 (0.3)           | 1 (0.8)          | - (0.0)           | - (0.0)           | - (0.0)            | 1 (3.8)                                                                                                   | 2 (0.3)                                                                                                                              |
| 516.35 Idiopathic lymphoid interstitial pneumonia                   |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.36 Cryptogenic organizing pneumonia                             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.37 Desquamative interstitial pneumonia                          |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |          | 5 (3.1)                                                                                                                               | 22 (5.9)          | 4 (3.1)          | 3 (6.5)           | - (0.0)           | 2 (4.5)            | 3 (11.5)                                                                                                  | 36 (4.7)                                                                                                                             |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |          | 9 (5.7)                                                                                                                               | 26 (6.9)          | 8 (6.3)          | 3 (6.5)           | - (0.0)           | 1 (2.3)            | - (0.0)                                                                                                   | 47 (6.1)                                                                                                                             |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 4. Age Distribution of Index Users, By Gender and Cohort, Through End of Current Period (Jul 2009 - Nov 2012), HealthCore Integrated Research Database (HIRD)** <sup>SM,1,2,3</sup>

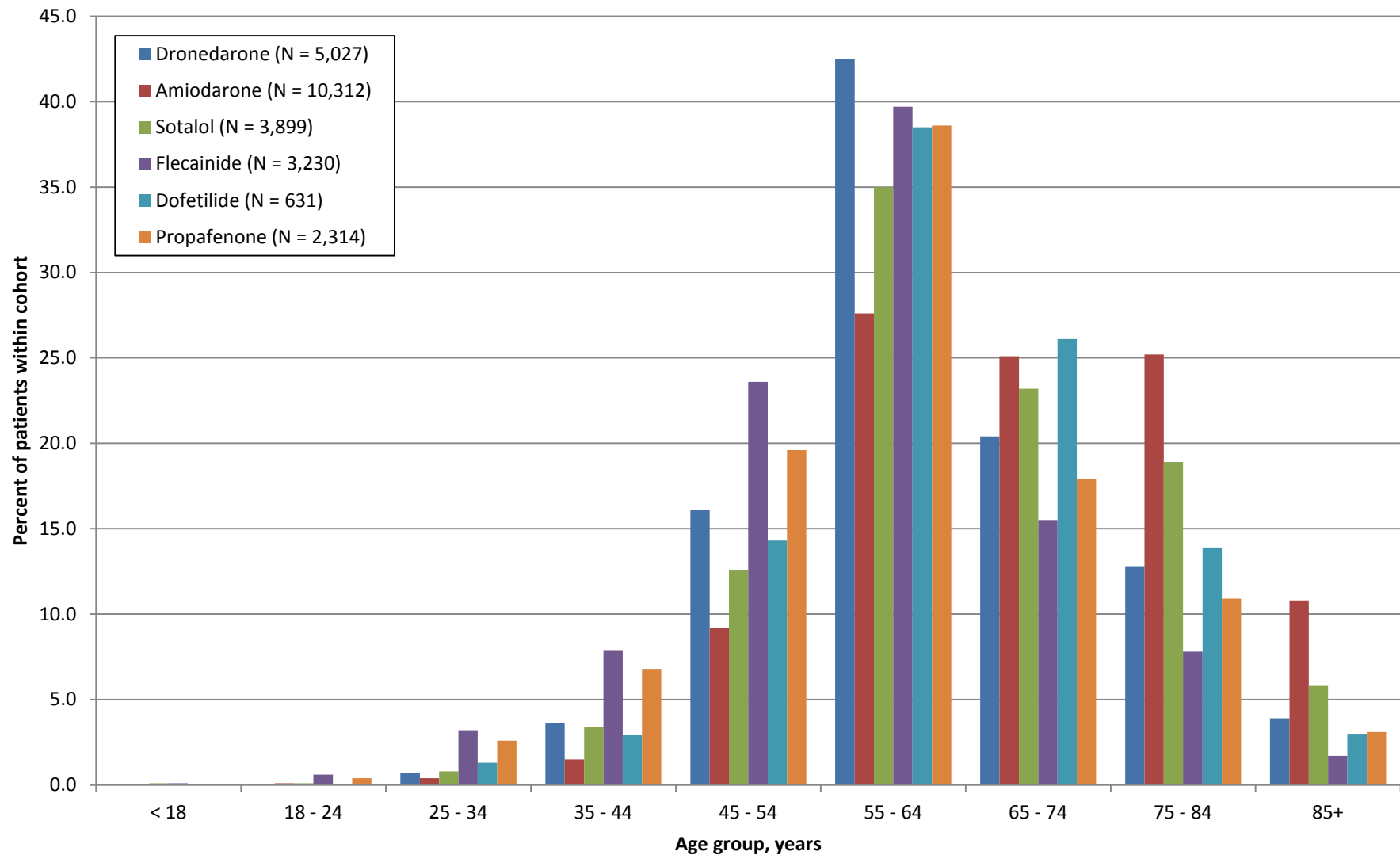
| Patients                                                                            | Dronedarone  |               | Amiodarone    |               | Sotalol      |               | Flecainide   |               | Dofetilide |              | Propafenone  |              | Total         |        |
|-------------------------------------------------------------------------------------|--------------|---------------|---------------|---------------|--------------|---------------|--------------|---------------|------------|--------------|--------------|--------------|---------------|--------|
|                                                                                     | 5,027        |               | 10,312        |               | 3,899        |               | 3,230        |               | 631        |              | 2,314        |              | 25,413        |        |
|                                                                                     | N            | (%)           | N             | (%)           | N            | (%)           | N            | (%)           | N          | (%)          | N            | (%)          | N             | (%)    |
| <b>Total patients identified through end of current period, Jul 2009 - Nov 2012</b> | <b>5,027</b> | <b>(19.8)</b> | <b>10,312</b> | <b>(40.6)</b> | <b>3,899</b> | <b>(15.3)</b> | <b>3,230</b> | <b>(12.7)</b> | <b>631</b> | <b>(2.5)</b> | <b>2,314</b> | <b>(9.1)</b> | <b>25,413</b> |        |
| Age group, years                                                                    |              |               |               |               |              |               |              |               |            |              |              |              |               |        |
| < 18                                                                                | 1            | (0.0)         | 4             | (0.0)         | 5            | (0.1)         | 3            | (0.1)         | -          | (0.0)        | -            | (0.0)        | 13            | (0.1)  |
| 18 - 24                                                                             | 2            | (0.0)         | 8             | (0.1)         | 4            | (0.1)         | 18           | (0.6)         | -          | (0.0)        | 9            | (0.4)        | 41            | (0.2)  |
| 25 - 34                                                                             | 35           | (0.7)         | 39            | (0.4)         | 33           | (0.8)         | 102          | (3.2)         | 8          | (1.3)        | 61           | (2.6)        | 278           | (1.1)  |
| 35 - 44                                                                             | 180          | (3.6)         | 159           | (1.5)         | 133          | (3.4)         | 254          | (7.9)         | 18         | (2.9)        | 157          | (6.8)        | 901           | (3.5)  |
| 45 - 54                                                                             | 810          | (16.1)        | 948           | (9.2)         | 492          | (12.6)        | 761          | (23.6)        | 90         | (14.3)       | 454          | (19.6)       | 3,555         | (14.0) |
| 55 - 64                                                                             | 2,136        | (42.5)        | 2,849         | (27.6)        | 1,365        | (35.0)        | 1,283        | (39.7)        | 243        | (38.5)       | 894          | (38.6)       | 8,770         | (34.5) |
| 65 - 74                                                                             | 1,025        | (20.4)        | 2,590         | (25.1)        | 904          | (23.2)        | 502          | (15.5)        | 165        | (26.1)       | 414          | (17.9)       | 5,600         | (22.0) |
| 75 - 84                                                                             | 643          | (12.8)        | 2,601         | (25.2)        | 736          | (18.9)        | 253          | (7.8)         | 88         | (13.9)       | 253          | (10.9)       | 4,574         | (18.0) |
| 85+                                                                                 | 195          | (3.9)         | 1,114         | (10.8)        | 227          | (5.8)         | 54           | (1.7)         | 19         | (3.0)        | 72           | (3.1)        | 1,681         | (6.6)  |
| Age group, female, years                                                            |              |               |               |               |              |               |              |               |            |              |              |              |               |        |
| < 18, female                                                                        | -            | (0.0)         | 2             | (0.1)         | 3            | (0.2)         | -            | (0.0)         | -          | (0.0)        | -            | (0.0)        | 5             | (0.1)  |
| 18 - 24, female                                                                     | -            | (0.0)         | 1             | (0.0)         | 1            | (0.1)         | 3            | (0.2)         | -          | (0.0)        | 2            | (0.2)        | 7             | (0.1)  |
| 25 - 34, female                                                                     | 9            | (0.5)         | 9             | (0.3)         | 6            | (0.4)         | 25           | (1.9)         | 2          | (1.0)        | 10           | (1.2)        | 61            | (0.7)  |
| 35 - 44, female                                                                     | 38           | (2.2)         | 28            | (0.8)         | 26           | (1.7)         | 68           | (5.2)         | 5          | (2.6)        | 30           | (3.6)        | 195           | (2.2)  |
| 45 - 54, female                                                                     | 165          | (9.7)         | 192           | (5.4)         | 129          | (8.6)         | 235          | (18.0)        | 15         | (7.7)        | 106          | (12.6)       | 842           | (9.3)  |
| 55 - 64, female                                                                     | 655          | (38.5)        | 674           | (19.1)        | 414          | (27.7)        | 495          | (38.0)        | 70         | (36.1)       | 326          | (38.7)       | 2,634         | (29.1) |
| 65 - 74, female                                                                     | 389          | (22.9)        | 811           | (23.0)        | 348          | (23.3)        | 260          | (20.0)        | 50         | (25.8)       | 178          | (21.1)       | 2,036         | (22.5) |
| 75 - 84, female                                                                     | 313          | (18.4)        | 1,153         | (32.7)        | 413          | (27.7)        | 172          | (13.2)        | 41         | (21.1)       | 141          | (16.7)       | 2,233         | (24.6) |
| 85+, female                                                                         | 132          | (7.8)         | 660           | (18.7)        | 153          | (10.2)        | 44           | (3.4)         | 11         | (5.7)        | 49           | (5.8)        | 1,049         | (11.6) |
| Age group, male, years                                                              |              |               |               |               |              |               |              |               |            |              |              |              |               |        |
| < 18, male                                                                          | 1            | (0.0)         | 2             | (0.0)         | 2            | (0.1)         | 3            | (0.2)         | -          | (0.0)        | -            | (0.0)        | 8             | (0.0)  |
| 18 - 24, male                                                                       | 2            | (0.1)         | 7             | (0.1)         | 3            | (0.1)         | 15           | (0.8)         | -          | (0.0)        | 7            | (0.5)        | 34            | (0.2)  |
| 25 - 34, male                                                                       | 26           | (0.8)         | 30            | (0.4)         | 27           | (1.1)         | 77           | (4.0)         | 6          | (1.4)        | 51           | (3.5)        | 217           | (1.3)  |
| 35 - 44, male                                                                       | 142          | (4.3)         | 131           | (1.9)         | 107          | (4.4)         | 186          | (9.6)         | 13         | (3.0)        | 127          | (8.6)        | 706           | (4.3)  |
| 45 - 54, male                                                                       | 645          | (19.4)        | 756           | (11.1)        | 363          | (15.1)        | 526          | (27.3)        | 75         | (17.2)       | 348          | (23.6)       | 2,713         | (16.6) |
| 55 - 64, male                                                                       | 1,481        | (44.5)        | 2,175         | (32.1)        | 951          | (39.5)        | 788          | (40.9)        | 173        | (39.6)       | 568          | (38.6)       | 6,136         | (37.5) |
| 65 - 74, male                                                                       | 636          | (19.1)        | 1,779         | (26.2)        | 556          | (23.1)        | 242          | (12.6)        | 115        | (26.3)       | 236          | (16.0)       | 3,564         | (21.8) |
| 75 - 84, male                                                                       | 330          | (9.9)         | 1,448         | (21.4)        | 323          | (13.4)        | 81           | (4.2)         | 47         | (10.8)       | 112          | (7.6)        | 2,341         | (14.3) |
| 85+, male                                                                           | 63           | (1.9)         | 454           | (6.7)         | 74           | (3.1)         | 10           | (0.5)         | 8          | (1.8)        | 23           | (1.6)        | 632           | (3.9)  |

1. This Table will be completed each quarter during the prospective count.

2. Only the index study drug will be counted, therefore a patient is only counted once.

3. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Nov 2012), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)**



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| Table 1. New Index Dronedaronone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD <sup>SM</sup> 1,2,3)                    |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------|--------------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|--------|--------|
| Patients                                                                                                                                                           | Dronedaronone |        | Amiodaronone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total  |        |
|                                                                                                                                                                    | N             | (%)    | N            | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N      | (%)    |
| Total patients identified through end of current period, Jul 2009 - Feb 2013 <sup>4</sup>                                                                          | 5,279         | (19.8) | 10,824       | (40.6) | 4,099   | (15.4) | 3,404      | (12.8) | 649        | (2.4)  | 2,415       | (9.1)  | 26,670 |        |
| Patients identified prior to current period, Jul 2009 - Nov 2012 <sup>4</sup>                                                                                      | 5,074         | (96.1) | 9,851        | (91.0) | 3,783   | (92.3) | 3,125      | (91.8) | 587        | (90.4) | 2,245       | (93.0) | 24,665 | (92.5) |
| New index patients identified during current period, Dec 2012 - Feb 2013                                                                                           | 205           | (3.9)  | 973          | (9.0)  | 316     | (7.7)  | 279        | (8.2)  | 62         | (9.6)  | 170         | (7.0)  | 2,005  | (7.5)  |
| 1. This Table will be completed each quarter during the prospective count.                                                                                         |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                            |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.         |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |               |        |              |        |         |        |            |        |            |        |             |        |        |        |

**Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM,1,2,3</sup>)**

| Events                                                                   | Patients | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Feb 2013) |              |              |               |            |              |            |              |            |              | Total SLI Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Dec 2012 - Feb 2013) |              | Cumulative Total SLI Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Feb 2013) |              |
|--------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|---------------|------------|--------------|------------|--------------|------------|--------------|-----------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                          |          | Dronedaron                                                                                                                            |              | Amiodaron    |               | Sotalol    |              | Flecainide |              | Dofetilide |              | Propafenone                                                                                               |              | Total                                                                                                                                |              |
|                                                                          |          | N                                                                                                                                     | (%)          | N            | (%)           | N          | (%)          | N          | (%)          | N          | (%)          | N                                                                                                         | (%)          | N                                                                                                                                    | (%)          |
| <b>Total<sup>1</sup></b>                                                 |          | <b>451</b>                                                                                                                            | <b>(8.5)</b> | <b>1,166</b> | <b>(10.8)</b> | <b>362</b> | <b>(8.8)</b> | <b>188</b> | <b>(5.5)</b> | <b>58</b>  | <b>(8.9)</b> | <b>177</b>                                                                                                | <b>(7.3)</b> | <b>47</b>                                                                                                                            | <b>(2.3)</b> |
| <b>Serious Liver Injury<sup>6</sup></b>                                  |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| <u>ICD-9-CM Diagnoses</u>                                                |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| 570.xx Acute and subacute necrosis of liver                              |          | 12                                                                                                                                    | (2.7)        | 40           | (3.4)         | 9          | (2.5)        | 5          | (2.7)        | 2          | (3.4)        | 1                                                                                                         | (0.6)        | -                                                                                                                                    | (0.0)        |
| 571.5x Cirrhosis of liver without mention of alcohol                     |          | 14                                                                                                                                    | (3.1)        | 43           | (3.7)         | 15         | (4.1)        | 9          | (4.8)        | 2          | (3.4)        | 6                                                                                                         | (3.4)        | 3                                                                                                                                    | (6.4)        |
| 572.2x Hepatic coma                                                      |          | 2                                                                                                                                     | (0.4)        | 5            | (0.4)         | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | 3                                                                                                         | (1.7)        | -                                                                                                                                    | (0.0)        |
| 572.4x Hepatorenal syndrome                                              |          | 1                                                                                                                                     | (0.2)        | 3            | (0.3)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.xx Other disorders of liver                                          |          | 131                                                                                                                                   | (29.0)       | 299          | (25.6)        | 108        | (29.8)       | 67         | (35.6)       | 18         | (31.0)       | 61                                                                                                        | (34.5)       | 9                                                                                                                                    | (19.1)       |
| 573.0x Chronic passive congestion of liver                               |          | 2                                                                                                                                     | (0.4)        | 18           | (1.5)         | 3          | (0.8)        | 1          | (0.5)        | 1          | (1.7)        | 1                                                                                                         | (0.6)        | -                                                                                                                                    | (0.0)        |
| 573.3x Hepatitis, unspecified                                            |          | 18                                                                                                                                    | (4.0)        | 57           | (4.9)         | 20         | (5.5)        | 10         | (5.3)        | 2          | (3.4)        | 8                                                                                                         | (4.5)        | -                                                                                                                                    | (0.0)        |
| 573.4x Hepatic infarction                                                |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.8x Other specified disorders of liver                                |          | 75                                                                                                                                    | (16.6)       | 155          | (13.3)        | 54         | (14.9)       | 45         | (23.9)       | 8          | (13.8)       | 41                                                                                                        | (23.2)       | 7                                                                                                                                    | (14.9)       |
| 573.9x Unspecified disorder of liver                                     |          | 38                                                                                                                                    | (8.4)        | 75           | (6.4)         | 34         | (9.4)        | 12         | (6.4)        | 9          | (15.5)       | 12                                                                                                        | (6.8)        | 2                                                                                                                                    | (4.3)        |
| 782.4x Jaundice, unspecified                                             |          | 10                                                                                                                                    | (2.2)        | 38           | (3.3)         | 9          | (2.5)        | 7          | (3.7)        | 1          | (1.7)        | 11                                                                                                        | (6.2)        | 2                                                                                                                                    | (4.3)        |
| 789.1x Hepatomegaly                                                      |          | 24                                                                                                                                    | (5.3)        | 37           | (3.2)         | 8          | (2.2)        | 10         | (5.3)        | 2          | (3.4)        | 9                                                                                                         | (5.1)        | -                                                                                                                                    | (0.0)        |
| 789.5x Ascites                                                           |          | 41                                                                                                                                    | (9.1)        | 232          | (19.9)        | 37         | (10.2)       | 11         | (5.9)        | 11         | (19.0)       | 16                                                                                                        | (9.0)        | 12                                                                                                                                   | (25.5)       |
| 790.4x Nonspecific elevation of levels of transaminase or LDH            |          | 77                                                                                                                                    | (17.1)       | 150          | (12.9)        | 46         | (12.7)       | 29         | (15.4)       | 6          | (10.3)       | 26                                                                                                        | (14.7)       | 5                                                                                                                                    | (10.6)       |
| 790.5x Other or nonspecified abnormal serum levels                       |          | 75                                                                                                                                    | (16.6)       | 186          | (16.0)        | 86         | (23.8)       | 24         | (12.8)       | 10         | (17.2)       | 20                                                                                                        | (11.3)       | 11                                                                                                                                   | (23.4)       |
| 791.4x Biliuria                                                          |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 794.8x Nonspecific abnormal results of liver function test               |          | 72                                                                                                                                    | (16.0)       | 136          | (11.7)        | 47         | (13.0)       | 26         | (13.8)       | 8          | (13.8)       | 24                                                                                                        | (13.6)       | 6                                                                                                                                    | (12.8)       |
| V42.7x Liver transplant status                                           |          | 3                                                                                                                                     | (0.7)        | 19           | (1.6)         | 5          | (1.4)        | 1          | (0.5)        | 2          | (3.4)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>ICD-9-CM Procedures</u>                                               |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                     |          | 1                                                                                                                                     | (0.2)        | 6            | (0.5)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.12 Open biopsy of liver                                               |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.13 Transjugular liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.14 Laparoscopic liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | 2            | (0.2)         | 2          | (0.6)        | -          | (0.0)        | -          | (0.0)        | 1                                                                                                         | (0.6)        | -                                                                                                                                    | (0.0)        |
| 50.5x Liver transplant                                                   |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.51 Auxiliary liver transplant                                         |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.59 Other transplant of liver                                          |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.91 Percutaneous aspiration of liver                                   |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>CPT Procedures</u>                                                    |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| CPT 47000 Biopsy of liver, needle; percutaneous                          |          | -                                                                                                                                     | (0.0)        | 3            | (0.3)         | 2          | (0.6)        | 2          | (1.1)        | 1          | (1.7)        | 1                                                                                                         | (0.6)        | -                                                                                                                                    | (0.0)        |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | 2          | (0.6)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47100 Biopsy of liver, wedge                                         |          | -                                                                                                                                     | (0.0)        | 1            | (0.1)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | 2                                                                                                         | (1.1)        | -                                                                                                                                    | (0.0)        |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole        |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole       |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78205 Liver imaging (SPECT)                                          |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | 2          | (1.1)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78206 Liver imaging (SPECT); with vascular flow                      |          | -                                                                                                                                     | (0.0)        | -            | (0.0)         | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>Laboratory Test Values</u>                                            |          |                                                                                                                                       |              |              |               |            |              |            |              |            |              |                                                                                                           |              |                                                                                                                                      |              |
| Elevation of alanine transaminase levels, 3x higher                      |          | 13                                                                                                                                    | (2.9)        | 24           | (2.1)         | 3          | (0.8)        | 1          | (0.5)        | 1          | (1.7)        | 3                                                                                                         | (1.7)        | 1                                                                                                                                    | (2.1)        |
| Elevation of aspartate transaminase levels, 3x higher                    |          | 4                                                                                                                                     | (0.9)        | 10           | (0.9)         | 1          | (0.3)        | 2          | (1.1)        | -          | (0.0)        | 2                                                                                                         | (1.1)        | -                                                                                                                                    | (0.0)        |
| Elevation of bilirubin level, 1.5x higher                                |          | 2                                                                                                                                     | (0.4)        | 5            | (0.4)         | 5          | (1.4)        | 3          | (1.6)        | -          | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLI cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD<sup>SM,1,2,3</sup>)**

| Events                                                              | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Feb 2013) |                   |                  |                   |                   |                    | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Dec 2012 - Feb 2013) | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Feb 2013) |
|---------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|-------------------|-------------------|--------------------|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
|                                                                     |          | <u>Dronedarone</u>                                                                                                                    | <u>Amiodarone</u> | <u>Sotalol</u>   | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u>                                                                                              | <u>Total</u>                                                                                                                         |
|                                                                     |          | 5,279                                                                                                                                 | 10,824            | 4,099            | 3,404             | 649               | 2,415              | 2,005                                                                                                     | 26,670                                                                                                                               |
|                                                                     |          | N (%)                                                                                                                                 | N (%)             | N (%)            | N (%)             | N (%)             | N (%)              | N (%)                                                                                                     | N (%)                                                                                                                                |
| <b>Total<sup>1</sup></b>                                            |          | <b>168 (3.2)</b>                                                                                                                      | <b>393 (3.6)</b>  | <b>132 (3.2)</b> | <b>56 (1.6)</b>   | <b>23 (3.5)</b>   | <b>50 (2.1)</b>    | <b>15 (0.7)</b>                                                                                           | <b>822 (3.1)</b>                                                                                                                     |
| Interstitial Lung Disease <sup>5</sup>                              |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |                                                                                                                                      |
| ICD-9-CM Diagnoses                                                  |          |                                                                                                                                       |                   |                  |                   |                   |                    |                                                                                                           |                                                                                                                                      |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |          | - (0.0)                                                                                                                               | 6 (1.5)           | 2 (1.5)          | 1 (1.8)           | - (0.0)           | 1 (2.0)            | - (0.0)                                                                                                   | 10 (1.2)                                                                                                                             |
| 515.xx Postinflammatory pulmonary fibrosis                          |          | 145 (86.3)                                                                                                                            | 306 (77.9)        | 112 (84.8)       | 42 (75.0)         | 20 (87.0)         | 43 (86.0)          | 14 (93.3)                                                                                                 | 668 (81.3)                                                                                                                           |
| 516.3x Idiopathic fibrosing alveolitis                              |          | 13 (7.7)                                                                                                                              | 38 (9.7)          | 12 (9.1)         | 7 (12.5)          | 3 (13.0)          | 4 (8.0)            | 1 (6.7)                                                                                                   | 77 (9.4)                                                                                                                             |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified   |          | 1 (0.6)                                                                                                                               | 1 (0.3)           | 1 (0.8)          | 1 (1.8)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | 4 (0.5)                                                                                                                              |
| 516.31 Idiopathic pulmonary fibrosis                                |          | 5 (3.0)                                                                                                                               | 13 (3.3)          | 2 (1.5)          | 2 (3.6)           | - (0.0)           | 1 (2.0)            | 1 (6.7)                                                                                                   | 23 (2.8)                                                                                                                             |
| 516.32 Idiopathic non-specific interstitial pneumonitis             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.33 Acute interstitial pneumonitis                               |          | - (0.0)                                                                                                                               | 2 (0.5)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | 2 (0.2)                                                                                                                              |
| 516.34 Respiratory bronchiolitis interstitial lung disease          |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.35 Idiopathic lymphoid interstitial pneumonia                   |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.36 Cryptogenic organizing pneumonia                             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.37 Desquamative interstitial pneumonia                          |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |          | 5 (3.0)                                                                                                                               | 25 (6.4)          | 3 (2.3)          | 3 (5.4)           | - (0.0)           | 3 (6.0)            | - (0.0)                                                                                                   | 39 (4.7)                                                                                                                             |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |          | 9 (5.4)                                                                                                                               | 26 (6.6)          | 7 (5.3)          | 3 (5.4)           | - (0.0)           | 1 (2.0)            | - (0.0)                                                                                                   | 46 (5.6)                                                                                                                             |

1. This Table will be completed each quarter during the prospective count.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

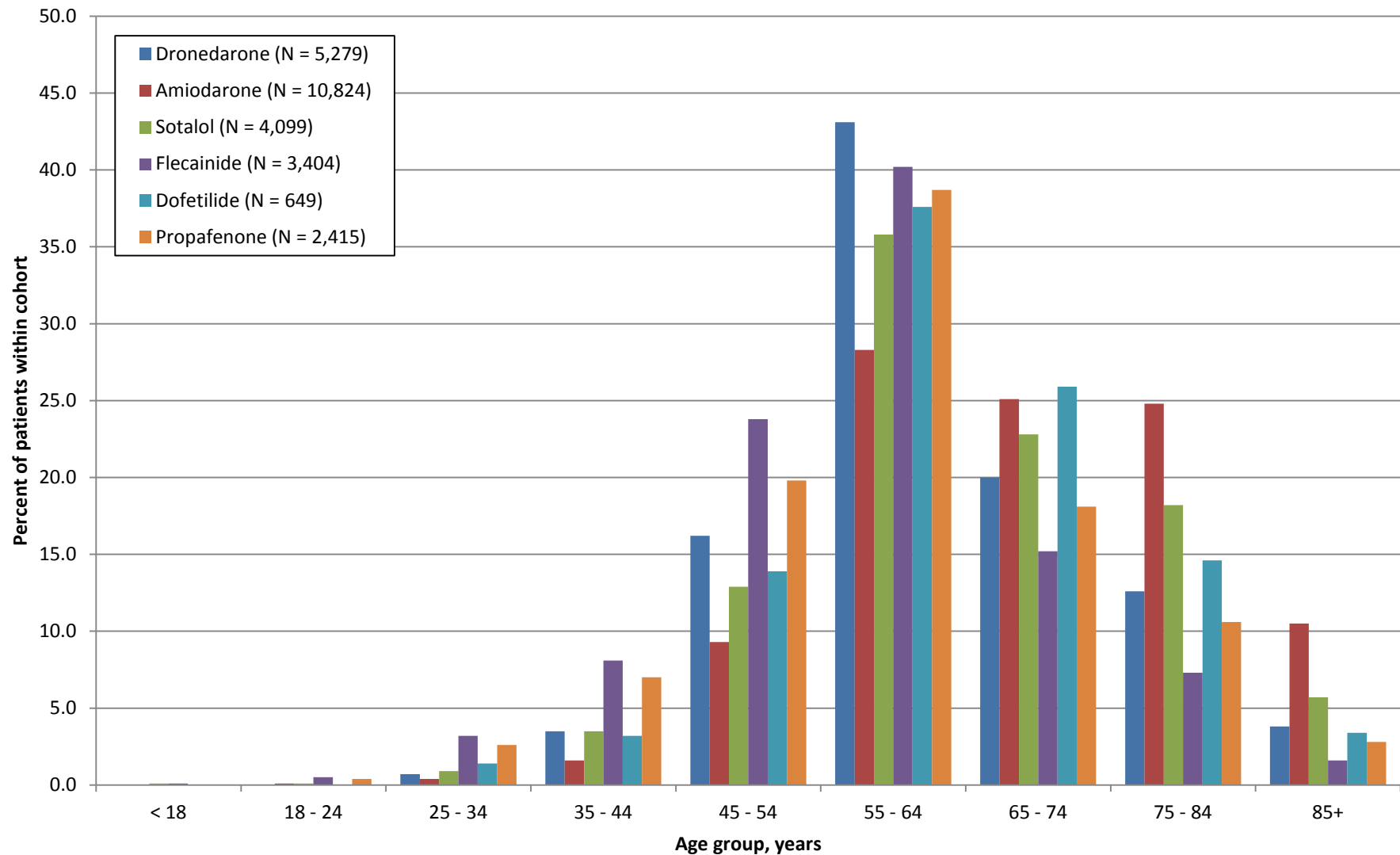
5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.



|                                                                                                                                                                    | <b>Dronedaron</b><br>5,279 |               | <b>Amiodarone</b><br>10,824 |               | <b>Sotalol</b><br>4,099 |               | <b>Flecainide</b><br>3,404 |               | <b>Dofetilide</b><br>649 |               | <b>Propafenone</b><br>2,415 |               | <b>Total</b><br>26,670 |               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|---------------|-----------------------------|---------------|-------------------------|---------------|----------------------------|---------------|--------------------------|---------------|-----------------------------|---------------|------------------------|---------------|
| <b>Patients</b>                                                                                                                                                    | <i>N</i>                   | (%)           | <i>N</i>                    | (%)           | <i>N</i>                | (%)           | <i>N</i>                   | (%)           | <i>N</i>                 | (%)           | <i>N</i>                    | (%)           | <i>N</i>               | (%)           |
| <b>Total patients identified through end of current period, Jul 2009 - Feb 2013</b>                                                                                | <b>5,279</b>               | <b>(19.8)</b> | <b>10,824</b>               | <b>(40.6)</b> | <b>4,099</b>            | <b>(15.4)</b> | <b>3,404</b>               | <b>(12.8)</b> | <b>649</b>               | <b>(2.4)</b>  | <b>2,415</b>                | <b>(9.1)</b>  | <b>26,670</b>          |               |
| <b>Age group, years</b>                                                                                                                                            |                            |               |                             |               |                         |               |                            |               |                          |               |                             |               |                        |               |
| < 18                                                                                                                                                               | 1                          | (0.0)         | 3                           | (0.0)         | 5                       | (0.1)         | 4                          | (0.1)         | -                        | (0.0)         | -                           | (0.0)         | 13                     | (0.0)         |
| 18 - 24                                                                                                                                                            | 2                          | (0.0)         | 9                           | (0.1)         | 3                       | (0.1)         | 18                         | (0.5)         | -                        | (0.0)         | 9                           | (0.4)         | 41                     | (0.2)         |
| 25 - 34                                                                                                                                                            | 38                         | (0.7)         | 41                          | (0.4)         | 36                      | (0.9)         | 108                        | (3.2)         | 9                        | (1.4)         | 63                          | (2.6)         | 295                    | (1.1)         |
| 35 - 44                                                                                                                                                            | 187                        | (3.5)         | 172                         | (1.6)         | 145                     | (3.5)         | 275                        | (8.1)         | 21                       | (3.2)         | 170                         | (7.0)         | 970                    | (3.6)         |
| 45 - 54                                                                                                                                                            | 854                        | (16.2)        | 1,004                       | (9.3)         | 529                     | (12.9)        | 810                        | (23.8)        | 90                       | (13.9)        | 477                         | (19.8)        | 3,764                  | (14.1)        |
| 55 - 64                                                                                                                                                            | 2,277                      | (43.1)        | 3,062                       | (28.3)        | 1,467                   | (35.8)        | 1,368                      | (40.2)        | 244                      | (37.6)        | 935                         | (38.7)        | 9,353                  | (35.1)        |
| 65 - 74                                                                                                                                                            | 1,057                      | (20.0)        | 2,719                       | (25.1)        | 935                     | (22.8)        | 518                        | (15.2)        | 168                      | (25.9)        | 438                         | (18.1)        | 5,835                  | (21.9)        |
| 75 - 84                                                                                                                                                            | 665                        | (12.6)        | 2,681                       | (24.8)        | 747                     | (18.2)        | 248                        | (7.3)         | 95                       | (14.6)        | 255                         | (10.6)        | 4,691                  | (17.6)        |
| 85+                                                                                                                                                                | 198                        | (3.8)         | 1,133                       | (10.5)        | 232                     | (5.7)         | 55                         | (1.6)         | 22                       | (3.4)         | 68                          | (2.8)         | 1,708                  | (6.4)         |
| <b>Age group, female, years</b>                                                                                                                                    | <b>1,790</b>               | <b>(33.9)</b> | <b>3,674</b>                | <b>(33.9)</b> | <b>1,565</b>            | <b>(38.2)</b> | <b>1,356</b>               | <b>(39.8)</b> | <b>202</b>               | <b>(31.1)</b> | <b>862</b>                  | <b>(35.7)</b> | <b>9,449</b>           | <b>(35.4)</b> |
| < 18, female                                                                                                                                                       | -                          | (0.0)         | 2                           | (0.1)         | 3                       | (0.2)         | -                          | (0.0)         | -                        | (0.0)         | -                           | (0.0)         | 5                      | (0.1)         |
| 18 - 24, female                                                                                                                                                    | -                          | (0.0)         | 2                           | (0.1)         | 1                       | (0.1)         | 3                          | (0.2)         | -                        | (0.0)         | 2                           | (0.2)         | 8                      | (0.1)         |
| 25 - 34, female                                                                                                                                                    | 9                          | (0.5)         | 10                          | (0.3)         | 7                       | (0.4)         | 24                         | (1.8)         | 3                        | (1.5)         | 12                          | (1.4)         | 65                     | (0.7)         |
| 35 - 44, female                                                                                                                                                    | 38                         | (2.1)         | 34                          | (0.9)         | 29                      | (1.9)         | 80                         | (5.9)         | 5                        | (2.5)         | 29                          | (3.4)         | 215                    | (2.3)         |
| 45 - 54, female                                                                                                                                                    | 178                        | (9.9)         | 205                         | (5.6)         | 136                     | (8.7)         | 249                        | (18.4)        | 18                       | (8.9)         | 109                         | (12.6)        | 895                    | (9.5)         |
| 55 - 64, female                                                                                                                                                    | 692                        | (38.7)        | 706                         | (19.2)        | 444                     | (28.4)        | 517                        | (38.1)        | 71                       | (35.1)        | 332                         | (38.5)        | 2,762                  | (29.2)        |
| 65 - 74, female                                                                                                                                                    | 410                        | (22.9)        | 848                         | (23.1)        | 374                     | (23.9)        | 267                        | (19.7)        | 53                       | (26.2)        | 189                         | (21.9)        | 2,141                  | (22.7)        |
| 75 - 84, female                                                                                                                                                    | 328                        | (18.3)        | 1,192                       | (32.4)        | 415                     | (26.5)        | 168                        | (12.4)        | 40                       | (19.8)        | 141                         | (16.4)        | 2,284                  | (24.2)        |
| 85+, female                                                                                                                                                        | 135                        | (7.5)         | 675                         | (18.4)        | 156                     | (10.0)        | 48                         | (3.5)         | 12                       | (5.9)         | 48                          | (5.6)         | 1,074                  | (11.4)        |
| <b>Age group, male, years</b>                                                                                                                                      | <b>3,489</b>               | <b>(66.1)</b> | <b>7,150</b>                | <b>(66.1)</b> | <b>2,534</b>            | <b>(61.8)</b> | <b>2,048</b>               | <b>(60.2)</b> | <b>447</b>               | <b>(68.9)</b> | <b>1,553</b>                | <b>(64.3)</b> | <b>17,221</b>          | <b>(64.6)</b> |
| < 18, male                                                                                                                                                         | 1                          | (0.0)         | 1                           | (0.0)         | 2                       | (0.1)         | 4                          | (0.2)         | -                        | (0.0)         | -                           | (0.0)         | 8                      | (0.0)         |
| 18 - 24, male                                                                                                                                                      | 2                          | (0.1)         | 7                           | (0.1)         | 2                       | (0.1)         | 15                         | (0.7)         | -                        | (0.0)         | 7                           | (0.5)         | 33                     | (0.2)         |
| 25 - 34, male                                                                                                                                                      | 29                         | (0.8)         | 31                          | (0.4)         | 29                      | (1.1)         | 84                         | (4.1)         | 6                        | (1.3)         | 51                          | (3.3)         | 230                    | (1.3)         |
| 35 - 44, male                                                                                                                                                      | 149                        | (4.3)         | 138                         | (1.9)         | 116                     | (4.6)         | 195                        | (9.5)         | 16                       | (3.6)         | 141                         | (9.1)         | 755                    | (4.4)         |
| 45 - 54, male                                                                                                                                                      | 676                        | (19.4)        | 799                         | (11.2)        | 393                     | (15.5)        | 561                        | (27.4)        | 72                       | (16.1)        | 368                         | (23.7)        | 2,869                  | (16.7)        |
| 55 - 64, male                                                                                                                                                      | 1,585                      | (45.4)        | 2,356                       | (33.0)        | 1,023                   | (40.4)        | 851                        | (41.6)        | 173                      | (38.7)        | 603                         | (38.8)        | 6,591                  | (38.3)        |
| 65 - 74, male                                                                                                                                                      | 647                        | (18.5)        | 1,871                       | (26.2)        | 561                     | (22.1)        | 251                        | (12.3)        | 115                      | (25.7)        | 249                         | (16.0)        | 3,694                  | (21.5)        |
| 75 - 84, male                                                                                                                                                      | 337                        | (9.7)         | 1,489                       | (20.8)        | 332                     | (13.1)        | 80                         | (3.9)         | 55                       | (12.3)        | 114                         | (7.3)         | 2,407                  | (14.0)        |
| 85+, male                                                                                                                                                          | 63                         | (1.8)         | 458                         | (6.4)         | 76                      | (3.0)         | 7                          | (0.3)         | 10                       | (2.2)         | 20                          | (1.3)         | 634                    | (3.7)         |
| 1. This Table will be completed each quarter during the prospective count.                                                                                         |                            |               |                             |               |                         |               |                            |               |                          |               |                             |               |                        |               |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                            |                            |               |                             |               |                         |               |                            |               |                          |               |                             |               |                        |               |
| 3. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |                            |               |                             |               |                         |               |                            |               |                          |               |                             |               |                        |               |

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Feb 2013), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)**



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| Table 1. New Index Dronedaronone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database (HIRD <sup>SM 1,2,3</sup> )                                         |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------|--------------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|--------|--------|
| Patients                                                                                                                                                                                 | Dronedaronone |        | Amiodaronone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total  |        |
|                                                                                                                                                                                          | N             | (%)    | N            | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N      | (%)    |
| Total patients identified through end of current period, Jul 2009 - May 2013 <sup>4</sup>                                                                                                | 3,988         | (18.6) | 9,304        | (43.5) | 3,089   | (14.4) | 2,662      | (12.4) | 557        | (2.6)  | 1,793       | (8.4)  | 21,393 |        |
| Patients identified prior to current period, Jul 2009 - Feb 2013 <sup>4</sup>                                                                                                            | 3,827         | (96.0) | 8,589        | (92.3) | 2,867   | (92.8) | 2,466      | (92.6) | 510        | (91.6) | 1,694       | (94.5) | 19,953 | (93.3) |
| New index patients identified during current period, Mar 2013 - May 2013                                                                                                                 | 161           | (4.0)  | 715          | (7.7)  | 222     | (7.2)  | 196        | (7.4)  | 47         | (8.4)  | 99          | (5.5)  | 1,440  | (6.7)  |
| 1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc. |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                                                  |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.                               |               |        |              |        |         |        |            |        |            |        |             |        |        |        |
| 4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.                       |               |        |              |        |         |        |            |        |            |        |             |        |        |        |

Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD)<sup>SM1,2,3</sup>

| Events                                                                   | Patients | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - May 2013) |              |                  |               |                |              |                   |              |                   |              | Total SLI Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Mar 2013 - May 2013) |              | Cumulative Total SLI Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - May 2013) |              |
|--------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------|---------------|----------------|--------------|-------------------|--------------|-------------------|--------------|-----------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                          |          | <u>Dronedaron</u>                                                                                                                     |              | <u>Amiodaron</u> |               | <u>Sotalol</u> |              | <u>Flecainide</u> |              | <u>Dofetilide</u> |              | <u>Propafenone</u>                                                                                        |              | <u>Total</u>                                                                                                                         |              |
|                                                                          |          | N                                                                                                                                     | (%)          | N                | (%)           | N              | (%)          | N                 | (%)          | N                 | (%)          | N                                                                                                         | (%)          | N                                                                                                                                    | (%)          |
| <b>Total<sup>5</sup></b>                                                 |          | <b>350</b>                                                                                                                            | <b>(8.8)</b> | <b>1,037</b>     | <b>(11.1)</b> | <b>252</b>     | <b>(8.2)</b> | <b>158</b>        | <b>(5.9)</b> | <b>52</b>         | <b>(9.3)</b> | <b>135</b>                                                                                                | <b>(7.5)</b> | <b>37</b>                                                                                                                            | <b>(2.6)</b> |
| <b>Serious Liver Injury<sup>6</sup></b>                                  |          |                                                                                                                                       |              |                  |               |                |              |                   |              |                   |              |                                                                                                           |              |                                                                                                                                      |              |
| <u>ICD-9-CM Diagnoses</u>                                                |          |                                                                                                                                       |              |                  |               |                |              |                   |              |                   |              |                                                                                                           |              |                                                                                                                                      |              |
| 570.xx Acute and subacute necrosis of liver                              |          | 9                                                                                                                                     | (2.6)        | 36               | (3.5)         | 8              | (3.2)        | 4                 | (2.5)        | 1                 | (1.9)        | 1                                                                                                         | (0.7)        | 3                                                                                                                                    | (8.1)        |
| 571.5x Cirrhosis of liver without mention of alcohol                     |          | 13                                                                                                                                    | (3.7)        | 42               | (4.1)         | 13             | (5.2)        | 10                | (6.3)        | 3                 | (5.8)        | 4                                                                                                         | (3.0)        | 5                                                                                                                                    | (13.5)       |
| 572.2x Hepatic coma                                                      |          | 2                                                                                                                                     | (0.6)        | 7                | (0.7)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | 2                                                                                                         | (1.5)        | 1                                                                                                                                    | (2.7)        |
| 572.4x Hepatorenal syndrome                                              |          | 1                                                                                                                                     | (0.3)        | 3                | (0.3)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.xx Other disorders of liver                                          |          | 105                                                                                                                                   | (30.0)       | 272              | (26.2)        | 77             | (30.6)       | 48                | (30.4)       | 19                | (36.5)       | 44                                                                                                        | (32.6)       | 4                                                                                                                                    | (10.8)       |
| 573.0x Chronic passive congestion of liver                               |          | 1                                                                                                                                     | (0.3)        | 17               | (1.6)         | 2              | (0.8)        | -                 | (0.0)        | 1                 | (1.9)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.3x Hepatitis, unspecified                                            |          | 14                                                                                                                                    | (4.0)        | 57               | (5.5)         | 9              | (3.6)        | 11                | (7.0)        | 2                 | (3.8)        | 7                                                                                                         | (5.2)        | 1                                                                                                                                    | (2.7)        |
| 573.4x Hepatic infarction                                                |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 573.8x Other specified disorders of liver                                |          | 64                                                                                                                                    | (18.3)       | 137              | (13.2)        | 38             | (15.1)       | 31                | (19.6)       | 11                | (21.2)       | 30                                                                                                        | (22.2)       | 2                                                                                                                                    | (5.4)        |
| 573.9x Unspecified disorder of liver                                     |          | 26                                                                                                                                    | (7.4)        | 66               | (6.4)         | 29             | (11.5)       | 6                 | (3.8)        | 5                 | (9.6)        | 8                                                                                                         | (5.9)        | 1                                                                                                                                    | (2.7)        |
| 782.4x Jaundice, unspecified                                             |          | 9                                                                                                                                     | (2.6)        | 29               | (2.8)         | 7              | (2.8)        | 8                 | (5.1)        | 1                 | (1.9)        | 8                                                                                                         | (5.9)        | -                                                                                                                                    | (0.0)        |
| 789.1x Hepatomegaly                                                      |          | 22                                                                                                                                    | (6.3)        | 32               | (3.1)         | 5              | (2.0)        | 6                 | (3.8)        | 3                 | (5.8)        | 7                                                                                                         | (5.2)        | 2                                                                                                                                    | (5.4)        |
| 789.5x Ascites                                                           |          | 35                                                                                                                                    | (10.0)       | 220              | (21.2)        | 25             | (9.9)        | 14                | (8.9)        | 5                 | (9.6)        | 10                                                                                                        | (7.4)        | 10                                                                                                                                   | (27.0)       |
| 790.4x Nonspecific elevation of levels of transaminase or LDH            |          | 54                                                                                                                                    | (15.4)       | 130              | (12.5)        | 30             | (11.9)       | 27                | (17.1)       | 4                 | (7.7)        | 20                                                                                                        | (14.8)       | -                                                                                                                                    | (0.0)        |
| 790.5x Other or nonspecified abnormal serum levels                       |          | 61                                                                                                                                    | (17.4)       | 160              | (15.4)        | 64             | (25.4)       | 25                | (15.8)       | 13                | (25.0)       | 18                                                                                                        | (13.3)       | 6                                                                                                                                    | (16.2)       |
| 791.4x Biliruria                                                         |          | -                                                                                                                                     | (0.0)        | 1                | (0.1)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 794.8x Nonspecific abnormal results of liver function test               |          | 52                                                                                                                                    | (14.9)       | 128              | (12.3)        | 27             | (10.7)       | 20                | (12.7)       | 5                 | (9.6)        | 21                                                                                                        | (15.6)       | 4                                                                                                                                    | (10.8)       |
| V42.7x Liver transplant status                                           |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>ICD-9-CM Procedures</u>                                               |          |                                                                                                                                       |              |                  |               |                |              |                   |              |                   |              |                                                                                                           |              |                                                                                                                                      |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                     |          | 1                                                                                                                                     | (0.3)        | 5                | (0.5)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.12 Open biopsy of liver                                               |          | 1                                                                                                                                     | (0.3)        | 1                | (0.1)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.13 Transjugular liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.14 Laparoscopic liver biopsy                                          |          | -                                                                                                                                     | (0.0)        | 1                | (0.1)         | 1              | (0.4)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.5x Liver transplant                                                   |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.51 Auxiliary liver transplant                                         |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.59 Other transplant of liver                                          |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.91 Percutaneous aspiration of liver                                   |          | -                                                                                                                                     | (0.0)        | 1                | (0.1)         | 1              | (0.4)        | -                 | (0.0)        | -                 | (0.0)        | 1                                                                                                         | (0.7)        | -                                                                                                                                    | (0.0)        |
| <u>CPT Procedures</u>                                                    |          |                                                                                                                                       |              |                  |               |                |              |                   |              |                   |              |                                                                                                           |              |                                                                                                                                      |              |
| CPT 47000 Biopsy of liver, needle; percutaneous                          |          | -                                                                                                                                     | (0.0)        | 6                | (0.6)         | 2              | (0.8)        | 2                 | (1.3)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | 1              | (0.4)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47100 Biopsy of liver, wedge                                         |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | 2                                                                                                         | (1.5)        | -                                                                                                                                    | (0.0)        |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole        |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole       |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78205 Liver imaging (SPECT)                                          |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| CPT 78206 Liver imaging (SPECT); with vascular flow                      |          | -                                                                                                                                     | (0.0)        | -                | (0.0)         | -              | (0.0)        | -                 | (0.0)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |
| <u>Laboratory Test Values</u>                                            |          |                                                                                                                                       |              |                  |               |                |              |                   |              |                   |              |                                                                                                           |              |                                                                                                                                      |              |
| Elevation of alanine transaminase levels, 3x higher                      |          | 11                                                                                                                                    | (3.1)        | 23               | (2.2)         | 1              | (0.4)        | -                 | (0.0)        | 1                 | (1.9)        | 2                                                                                                         | (1.5)        | 2                                                                                                                                    | (5.4)        |
| Elevation of aspartate transaminase levels, 3x higher                    |          | 4                                                                                                                                     | (1.1)        | 7                | (0.7)         | -              | (0.0)        | 1                 | (0.6)        | -                 | (0.0)        | 2                                                                                                         | (1.5)        | -                                                                                                                                    | (0.0)        |
| Elevation of bilirubin level, 1.5x higher                                |          | 1                                                                                                                                     | (0.3)        | 3                | (0.3)         | 3              | (1.2)        | 2                 | (1.3)        | -                 | (0.0)        | -                                                                                                         | (0.0)        | -                                                                                                                                    | (0.0)        |

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2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLI cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database (HIRD)<sup>SM,1,2,3</sup>

| Events                                                              | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - May 2013) |                   |                 |                   |                   |                    | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Mar 2013 - May 2013) |  | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - May 2013) |  |
|---------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------|-------------------|-------------------|--------------------|-----------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                     |          | <u>Dronedarone</u>                                                                                                                    | <u>Amiodarone</u> | <u>Sotalol</u>  | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u>                                                                                              |  | <u>Total</u>                                                                                                                         |  |
|                                                                     |          | <i>N</i> (%)                                                                                                                          | <i>N</i> (%)      | <i>N</i> (%)    | <i>N</i> (%)      | <i>N</i> (%)      | <i>N</i> (%)       | <i>N</i> (%)                                                                                              |  | <i>N</i> (%)                                                                                                                         |  |
| <b>Total<sup>5</sup></b>                                            |          | <b>122 (3.1)</b>                                                                                                                      | <b>355 (3.8)</b>  | <b>93 (3.0)</b> | <b>42 (1.6)</b>   | <b>18 (3.2)</b>   | <b>37 (2.1)</b>    | <b>18 (1.3)</b>                                                                                           |  | <b>667 (3.1)</b>                                                                                                                     |  |
| Interstitial Lung Disease <sup>6</sup>                              |          |                                                                                                                                       |                   |                 |                   |                   |                    |                                                                                                           |  |                                                                                                                                      |  |
| ICD-9-CM Diagnoses                                                  |          |                                                                                                                                       |                   |                 |                   |                   |                    |                                                                                                           |  |                                                                                                                                      |  |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |          | 2 (1.6)                                                                                                                               | 3 (0.8)           | 2 (2.2)         | 1 (2.4)           | - (0.0)           | 1 (2.7)            | - (0.0)                                                                                                   |  | 9 (1.3)                                                                                                                              |  |
| 515.xx Postinflammatory pulmonary fibrosis                          |          | 103 (84.4)                                                                                                                            | 270 (76.1)        | 79 (84.9)       | 31 (73.8)         | 15 (83.3)         | 31 (83.8)          | 12 (66.7)                                                                                                 |  | 529 (79.3)                                                                                                                           |  |
| 516.3x Idiopathic fibrosing alveolitis                              |          | 13 (10.7)                                                                                                                             | 43 (12.1)         | 7 (7.5)         | 7 (16.7)          | 3 (16.7)          | 4 (10.8)           | 4 (22.2)                                                                                                  |  | 77 (11.5)                                                                                                                            |  |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified   |          | 1 (0.8)                                                                                                                               | 3 (0.8)           | - (0.0)         | 1 (2.4)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | 5 (0.7)                                                                                                                              |  |
| 516.31 Idiopathic pulmonary fibrosis                                |          | 4 (3.3)                                                                                                                               | 16 (4.5)          | 1 (1.1)         | 2 (4.8)           | 1 (5.6)           | 1 (2.7)            | 3 (16.7)                                                                                                  |  | 25 (3.7)                                                                                                                             |  |
| 516.32 Idiopathic non-specific interstitial pneumonitis             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)         | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | - (0.0)                                                                                                                              |  |
| 516.33 Acute interstitial pneumonitis                               |          | - (0.0)                                                                                                                               | 3 (0.8)           | - (0.0)         | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | 3 (0.4)                                                                                                                              |  |
| 516.34 Respiratory bronchiolitis interstitial lung disease          |          | 1 (0.8)                                                                                                                               | - (0.0)           | - (0.0)         | - (0.0)           | - (0.0)           | - (0.0)            | 1 (5.6)                                                                                                   |  | 1 (0.1)                                                                                                                              |  |
| 516.35 Idiopathic lymphoid interstitial pneumonia                   |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)         | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | - (0.0)                                                                                                                              |  |
| 516.36 Cryptogenic organizing pneumonia                             |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)         | 1 (2.4)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | 1 (0.1)                                                                                                                              |  |
| 516.37 Desquamative interstitial pneumonia                          |          | - (0.0)                                                                                                                               | - (0.0)           | - (0.0)         | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | - (0.0)                                                                                                                              |  |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |          | 2 (1.6)                                                                                                                               | 25 (7.0)          | 3 (3.2)         | 1 (2.4)           | - (0.0)           | 3 (8.1)            | 2 (11.1)                                                                                                  |  | 34 (5.1)                                                                                                                             |  |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |          | 6 (4.9)                                                                                                                               | 21 (5.9)          | 4 (4.3)         | 2 (4.8)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |  | 33 (4.9)                                                                                                                             |  |

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2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

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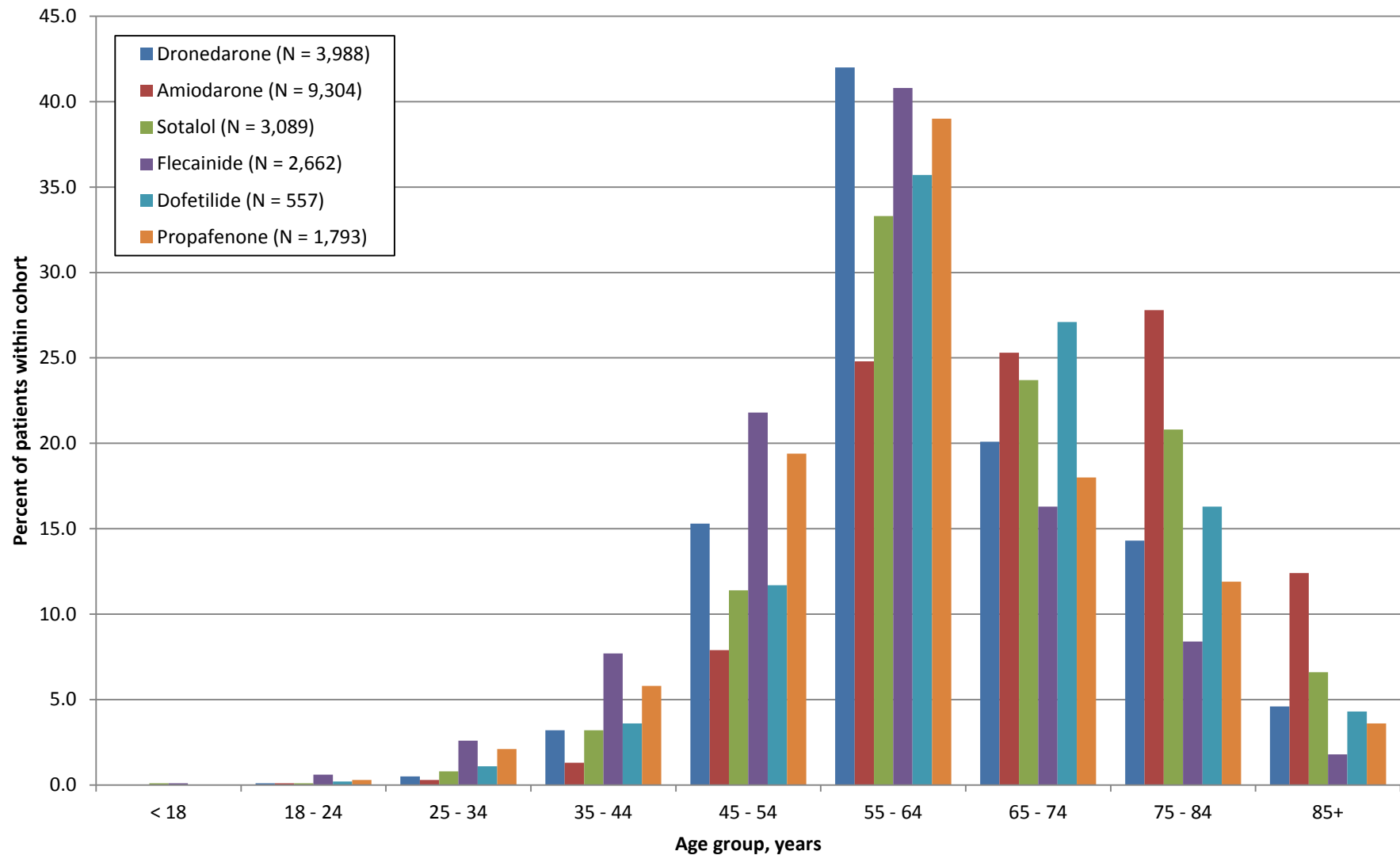
4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

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6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

| Patients                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Dronedarone</b><br><b>3,988</b> |               | <b>Amiodarone</b><br><b>9,304</b> |               | <b>Sotalol</b><br><b>3,089</b> |               | <b>Flecainide</b><br><b>2,662</b> |               | <b>Dofetilide</b><br><b>557</b> |              | <b>Propafenone</b><br><b>1,793</b> |              | <b>Total</b><br><b>21,393</b> |        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|---------------|-----------------------------------|---------------|--------------------------------|---------------|-----------------------------------|---------------|---------------------------------|--------------|------------------------------------|--------------|-------------------------------|--------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                           | N                                  | (%)           | N                                 | (%)           | N                              | (%)           | N                                 | (%)           | N                               | (%)          | N                                  | (%)          | N                             | (%)    |
| <b>Total patients identified through end of current period, Jul 2009 - May 2013</b>                                                                                                                                                                                                                                                                                                                                                                       | <b>3,988</b>                       | <b>(18.6)</b> | <b>9,304</b>                      | <b>(43.5)</b> | <b>3,089</b>                   | <b>(14.4)</b> | <b>2,662</b>                      | <b>(12.4)</b> | <b>557</b>                      | <b>(2.6)</b> | <b>1,793</b>                       | <b>(8.4)</b> | <b>21,393</b>                 |        |
| Age group, years                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                    |               |                                   |               |                                |               |                                   |               |                                 |              |                                    |              |                               |        |
| < 18                                                                                                                                                                                                                                                                                                                                                                                                                                                      | -                                  | (0.0)         | 2                                 | (0.0)         | 4                              | (0.1)         | 2                                 | (0.1)         | -                               | (0.0)        | -                                  | (0.0)        | 8                             | (0.0)  |
| 18 - 24                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2                                  | (0.1)         | 5                                 | (0.1)         | 2                              | (0.1)         | 15                                | (0.6)         | 1                               | (0.2)        | 5                                  | (0.3)        | 30                            | (0.1)  |
| 25 - 34                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 21                                 | (0.5)         | 28                                | (0.3)         | 26                             | (0.8)         | 69                                | (2.6)         | 6                               | (1.1)        | 37                                 | (2.1)        | 187                           | (0.9)  |
| 35 - 44                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 126                                | (3.2)         | 123                               | (1.3)         | 98                             | (3.2)         | 206                               | (7.7)         | 20                              | (3.6)        | 104                                | (5.8)        | 677                           | (3.2)  |
| 45 - 54                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 610                                | (15.3)        | 738                               | (7.9)         | 353                            | (11.4)        | 579                               | (21.8)        | 65                              | (11.7)       | 347                                | (19.4)       | 2,692                         | (12.6) |
| 55 - 64                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1,675                              | (42.0)        | 2,311                             | (24.8)        | 1,029                          | (33.3)        | 1,086                             | (40.8)        | 199                             | (35.7)       | 699                                | (39.0)       | 6,999                         | (32.7) |
| 65 - 74                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 801                                | (20.1)        | 2,357                             | (25.3)        | 731                            | (23.7)        | 433                               | (16.3)        | 151                             | (27.1)       | 322                                | (18.0)       | 4,795                         | (22.4) |
| 75 - 84                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 570                                | (14.3)        | 2,589                             | (27.8)        | 641                            | (20.8)        | 223                               | (8.4)         | 91                              | (16.3)       | 214                                | (11.9)       | 4,328                         | (20.2) |
| 85+                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 183                                | (4.6)         | 1,151                             | (12.4)        | 205                            | (6.6)         | 49                                | (1.8)         | 24                              | (4.3)        | 65                                 | (3.6)        | 1,677                         | (7.8)  |
| Age group, female, years                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |               |                                   |               |                                |               |                                   |               |                                 |              |                                    |              |                               |        |
| < 18, female                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                                  | (0.0)         | 2                                 | (0.1)         | 3                              | (0.2)         | -                                 | (0.0)         | -                               | (0.0)        | -                                  | (0.0)        | 5                             | (0.1)  |
| 18 - 24, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | -                                  | (0.0)         | 2                                 | (0.1)         | -                              | (0.0)         | 2                                 | (0.2)         | 1                               | (0.5)        | -                                  | (0.0)        | 5                             | (0.1)  |
| 25 - 34, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3                                  | (0.2)         | 6                                 | (0.2)         | 9                              | (0.7)         | 14                                | (1.3)         | 2                               | (1.1)        | 9                                  | (1.4)        | 43                            | (0.5)  |
| 35 - 44, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 21                                 | (1.6)         | 23                                | (0.7)         | 17                             | (1.4)         | 59                                | (5.6)         | 5                               | (2.7)        | 16                                 | (2.5)        | 141                           | (1.8)  |
| 45 - 54, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 124                                | (9.2)         | 147                               | (4.4)         | 92                             | (7.4)         | 157                               | (15.0)        | 12                              | (6.5)        | 66                                 | (10.2)       | 598                           | (7.6)  |
| 55 - 64, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 473                                | (35.1)        | 517                               | (15.3)        | 303                            | (24.5)        | 397                               | (38.0)        | 56                              | (30.4)       | 241                                | (37.2)       | 1,987                         | (25.4) |
| 65 - 74, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 305                                | (22.7)        | 779                               | (23.1)        | 312                            | (25.3)        | 223                               | (21.3)        | 51                              | (27.7)       | 153                                | (23.6)       | 1,823                         | (23.3) |
| 75 - 84, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 287                                | (21.3)        | 1,196                             | (35.4)        | 354                            | (28.7)        | 149                               | (14.3)        | 43                              | (23.4)       | 121                                | (18.7)       | 2,150                         | (27.5) |
| 85+, female                                                                                                                                                                                                                                                                                                                                                                                                                                               | 133                                | (9.9)         | 702                               | (20.8)        | 145                            | (11.7)        | 44                                | (4.2)         | 14                              | (7.6)        | 42                                 | (6.5)        | 1,080                         | (13.8) |
| Age group, male, years                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                    |               |                                   |               |                                |               |                                   |               |                                 |              |                                    |              |                               |        |
| < 18, male                                                                                                                                                                                                                                                                                                                                                                                                                                                | -                                  | (0.0)         | -                                 | (0.0)         | 1                              | (0.1)         | 2                                 | (0.1)         | -                               | (0.0)        | -                                  | (0.0)        | 3                             | (0.0)  |
| 18 - 24, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 2                                  | (0.1)         | 3                                 | (0.1)         | 2                              | (0.1)         | 13                                | (0.8)         | -                               | (0.0)        | 5                                  | (0.4)        | 25                            | (0.2)  |
| 25 - 34, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 18                                 | (0.7)         | 22                                | (0.4)         | 17                             | (0.9)         | 55                                | (3.4)         | 4                               | (1.1)        | 28                                 | (2.4)        | 144                           | (1.1)  |
| 35 - 44, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 105                                | (4.0)         | 100                               | (1.7)         | 81                             | (4.4)         | 147                               | (9.1)         | 15                              | (4.0)        | 88                                 | (7.7)        | 536                           | (4.0)  |
| 45 - 54, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 486                                | (18.4)        | 591                               | (10.0)        | 261                            | (14.1)        | 422                               | (26.1)        | 53                              | (14.2)       | 281                                | (24.5)       | 2,094                         | (15.4) |
| 55 - 64, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1,202                              | (45.5)        | 1,794                             | (30.3)        | 726                            | (39.2)        | 689                               | (42.6)        | 143                             | (38.3)       | 458                                | (40.0)       | 5,012                         | (37.0) |
| 65 - 74, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 496                                | (18.8)        | 1,578                             | (26.6)        | 419                            | (22.6)        | 210                               | (13.0)        | 100                             | (26.8)       | 169                                | (14.8)       | 2,972                         | (21.9) |
| 75 - 84, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 283                                | (10.7)        | 1,393                             | (23.5)        | 287                            | (15.5)        | 74                                | (4.6)         | 48                              | (12.9)       | 93                                 | (8.1)        | 2,178                         | (16.1) |
| 85+, male                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 50                                 | (1.9)         | 449                               | (7.6)         | 60                             | (3.2)         | 5                                 | (0.3)         | 10                              | (2.7)        | 23                                 | (2.0)        | 597                           | (4.4)  |
| 1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc.<br>2. Only the index study drug will be counted, therefore a patient is only counted once.<br>3. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |                                    |               |                                   |               |                                |               |                                   |               |                                 |              |                                    |              |                               |        |

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - May 2013), HealthCore Integrated Research Database (HIRD<sup>SM</sup>)**





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Figure 1. Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Nov 2013), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

| <b>Table 1. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                    |               |                   |               |                |               |                   |               |                   |               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|-------------------|---------------|----------------|---------------|-------------------|---------------|-------------------|---------------|
| <b>Patients</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Dronedarone</b> |               | <b>Amiodarone</b> |               | <b>Sotalol</b> |               | <b>Flecainide</b> |               | <b>Dofetilide</b> |               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>N</i>           | (%)           | <i>N</i>          | (%)           | <i>N</i>       | (%)           | <i>N</i>          | (%)           | <i>N</i>          | (%)           |
| <b>Total patients identified through end of current period, Jul 2009 - Nov 2013<sup>4</sup></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>4,245</b>       | <b>(17.7)</b> | <b>10,582</b>     | <b>(44.1)</b> | <b>3,491</b>   | <b>(14.6)</b> | <b>3,019</b>      | <b>(12.6)</b> | <b>638</b>        | <b>(2.7)</b>  |
| Patients identified prior to current period, Jul 2009 - May 2013 <sup>4</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3,978              | (93.7)        | 9,212             | (87.1)        | 3,059          | (87.6)        | 2,613             | (86.6)        | 548               | (85.9)        |
| New index patients identified during current period, Jun 2013 - Nov 2013                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 267                | (6.3)         | 1,370             | (12.9)        | 432            | (12.4)        | 406               | (13.4)        | 90                | (14.1)        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    |               |                   |               |                |               |                   |               | 216               | (10.8)        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    |               |                   |               |                |               |                   |               | <b>2,781</b>      | <b>(11.6)</b> |
| 1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc.<br>2. Only the index study drug will be counted, therefore a patient is only counted once.<br>3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.<br>4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |                    |               |                   |               |                |               |                   |               |                   |               |

| Table 2. Serious Liver Injury (SLI) Counts, By Cohort and Period, HealthCore Integrated Research Database <sup>SM</sup> (HIRD) <sup>1,2,3</sup> |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------|-------------------|-------------------|--------------------|-----------------------------------------------------------------------------------------------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------|-------|
| Events                                                                                                                                          | Patients | Cumulative SLI Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2013) |                     |                  |                   |                   |                    | Total SLI Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Jun 2013 - Nov 2013) |       | Cumulative Total SLI Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2013) |       |
|                                                                                                                                                 |          | <u>Dronedarone</u>                                                                                                                    | <u>Amiodarone</u>   | <u>Sotalol</u>   | <u>Flecainide</u> | <u>Dofetilide</u> | <u>Propafenone</u> | <u>Total</u>                                                                                              |       | <u>Total</u>                                                                                                                         |       |
|                                                                                                                                                 |          | N (%)                                                                                                                                 | N (%)               | N (%)            | N (%)             | N (%)             | N (%)              | N (%)                                                                                                     | N (%) | N (%)                                                                                                                                | N (%) |
| <b>Total<sup>5</sup></b>                                                                                                                        |          | <b>392 (9.2)</b>                                                                                                                      | <b>1,234 (11.7)</b> | <b>314 (9.0)</b> | <b>176 (5.8)</b>  | <b>58 (9.1)</b>   | <b>151 (7.6)</b>   | <b>107 (3.8)</b>                                                                                          |       | <b>2,325 (9.7)</b>                                                                                                                   |       |
| <u>Serious Liver Injury<sup>6</sup></u>                                                                                                         |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
| <u>ICD-9-CM Diagnoses</u>                                                                                                                       |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
| 570.xx Acute and subacute necrosis of liver                                                                                                     |          | 11 (2.8)                                                                                                                              | 49 (4.0)            | 10 (3.2)         | 4 (2.3)           | 1 (1.7)           | 2 (1.3)            | 7 (6.5)                                                                                                   |       | 77 (3.3)                                                                                                                             |       |
| 571.5x Cirrhosis of liver without mention of alcohol                                                                                            |          | 14 (3.6)                                                                                                                              | 53 (4.3)            | 16 (5.1)         | 11 (6.3)          | 3 (5.2)           | 6 (4.0)            | 10 (9.3)                                                                                                  |       | 103 (4.4)                                                                                                                            |       |
| 572.2x Hepatic coma                                                                                                                             |          | 2 (0.5)                                                                                                                               | 8 (0.6)             | - (0.0)          | - (0.0)           | - (0.0)           | 2 (1.3)            | 1 (0.9)                                                                                                   |       | 12 (0.5)                                                                                                                             |       |
| 572.4x Hepatorenal syndrome                                                                                                                     |          | - (0.0)                                                                                                                               | 3 (0.2)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 3 (0.1)                                                                                                                              |       |
| 573.xx Other disorders of liver                                                                                                                 |          | 118 (30.1)                                                                                                                            | 311 (25.2)          | 90 (28.7)        | 53 (30.1)         | 17 (29.3)         | 47 (31.1)          | 27 (25.2)                                                                                                 |       | 636 (27.4)                                                                                                                           |       |
| 573.0x Chronic passive congestion of liver                                                                                                      |          | 1 (0.3)                                                                                                                               | 18 (1.5)            | 3 (1.0)          | - (0.0)           | - (0.0)           | - (0.0)            | 2 (1.9)                                                                                                   |       | 22 (0.9)                                                                                                                             |       |
| 573.3x Hepatitis, unspecified                                                                                                                   |          | 17 (4.3)                                                                                                                              | 61 (4.9)            | 10 (3.2)         | 12 (6.8)          | 3 (5.2)           | 7 (4.6)            | 4 (3.7)                                                                                                   |       | 110 (4.7)                                                                                                                            |       |
| 573.4x Hepatic infarction                                                                                                                       |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| 573.8x Other specified disorders of liver                                                                                                       |          | 69 (17.6)                                                                                                                             | 160 (13.0)          | 47 (15.0)        | 35 (19.9)         | 9 (15.5)          | 31 (20.5)          | 15 (14.0)                                                                                                 |       | 351 (15.1)                                                                                                                           |       |
| 573.9x Unspecified disorder of liver                                                                                                            |          | 31 (7.9)                                                                                                                              | 78 (6.3)            | 30 (9.6)         | 6 (3.4)           | 5 (8.6)           | 9 (6.0)            | 5 (4.7)                                                                                                   |       | 159 (6.8)                                                                                                                            |       |
| 782.4x Jaundice, unspecified                                                                                                                    |          | 12 (3.1)                                                                                                                              | 44 (3.6)            | 9 (2.9)          | 9 (5.1)           | 4 (6.9)           | 9 (6.0)            | 8 (7.5)                                                                                                   |       | 87 (3.7)                                                                                                                             |       |
| 789.1x Hepatomegaly                                                                                                                             |          | 25 (6.4)                                                                                                                              | 38 (3.1)            | 10 (3.2)         | 7 (4.0)           | 2 (3.4)           | 6 (4.0)            | 3 (2.8)                                                                                                   |       | 88 (3.8)                                                                                                                             |       |
| 789.5x Ascites                                                                                                                                  |          | 41 (10.5)                                                                                                                             | 257 (20.8)          | 31 (9.9)         | 17 (9.7)          | 8 (13.8)          | 14 (9.3)           | 20 (18.7)                                                                                                 |       | 368 (15.8)                                                                                                                           |       |
| 790.4x Nonspecific elevation of levels of transaminase or LDH                                                                                   |          | 62 (15.8)                                                                                                                             | 158 (12.8)          | 39 (12.4)        | 33 (18.8)         | 4 (6.9)           | 21 (13.9)          | 17 (15.9)                                                                                                 |       | 317 (13.6)                                                                                                                           |       |
| 790.5x Other or nonspecified abnormal serum levels                                                                                              |          | 70 (17.9)                                                                                                                             | 196 (15.9)          | 82 (26.1)        | 27 (15.3)         | 16 (27.6)         | 21 (13.9)          | 20 (18.7)                                                                                                 |       | 412 (17.7)                                                                                                                           |       |
| 791.4x Bilirubin                                                                                                                                |          | - (0.0)                                                                                                                               | 1 (0.1)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 1 (0.0)                                                                                                                              |       |
| 794.8x Nonspecific abnormal results of liver function test                                                                                      |          | 54 (13.8)                                                                                                                             | 144 (11.7)          | 35 (11.1)        | 20 (11.4)         | 5 (8.6)           | 24 (15.9)          | 4 (3.7)                                                                                                   |       | 282 (12.1)                                                                                                                           |       |
| V42.7x Liver transplant status                                                                                                                  |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| <u>ICD-9-CM Procedures</u>                                                                                                                      |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                                                                                            |          | 1 (0.3)                                                                                                                               | 5 (0.4)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 6 (0.3)                                                                                                                              |       |
| 50.12 Open biopsy of liver                                                                                                                      |          | 1 (0.3)                                                                                                                               | 1 (0.1)             | 1 (0.3)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 3 (0.1)                                                                                                                              |       |
| 50.13 Transjugular liver biopsy                                                                                                                 |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| 50.14 Laparoscopic liver biopsy                                                                                                                 |          | - (0.0)                                                                                                                               | 1 (0.1)             | 1 (0.3)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 2 (0.1)                                                                                                                              |       |
| 50.5x Liver transplant                                                                                                                          |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| 50.51 Auxiliary liver transplant                                                                                                                |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| 50.59 Other transplant of liver                                                                                                                 |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| 50.91 Percutaneous aspiration of liver                                                                                                          |          | - (0.0)                                                                                                                               | 2 (0.2)             | 1 (0.3)          | - (0.0)           | - (0.0)           | 1 (0.7)            | - (0.0)                                                                                                   |       | 4 (0.2)                                                                                                                              |       |
| <u>CPT Procedures</u>                                                                                                                           |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
| CPT 47000 Biopsy of liver, needle; percutaneous                                                                                                 |          | - (0.0)                                                                                                                               | 6 (0.5)             | 2 (0.6)          | 2 (1.1)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 10 (0.4)                                                                                                                             |       |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure                                                                        |          | - (0.0)                                                                                                                               | - (0.0)             | 1 (0.3)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 1 (0.0)                                                                                                                              |       |
| CPT 47100 Biopsy of liver, wedge                                                                                                                |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | 2 (1.3)            | - (0.0)                                                                                                   |       | 2 (0.1)                                                                                                                              |       |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole                                                                               |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole                                                                              |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| CPT 78205 Liver imaging (SPECT)                                                                                                                 |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| CPT 78206 Liver imaging (SPECT); with vascular flow                                                                                             |          | - (0.0)                                                                                                                               | - (0.0)             | - (0.0)          | - (0.0)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | - (0.0)                                                                                                                              |       |
| <u>Laboratory Test Values</u>                                                                                                                   |          |                                                                                                                                       |                     |                  |                   |                   |                    |                                                                                                           |       |                                                                                                                                      |       |
| Elevation of alanine transaminase levels, 3x higher                                                                                             |          | 10 (2.6)                                                                                                                              | 26 (2.1)            | 3 (1.0)          | - (0.0)           | 1 (1.7)           | 2 (1.3)            | 1 (0.9)                                                                                                   |       | 42 (1.8)                                                                                                                             |       |
| Elevation of aspartate transaminase levels, 3x higher                                                                                           |          | 4 (1.0)                                                                                                                               | 11 (0.9)            | 1 (0.3)          | 1 (0.6)           | - (0.0)           | 2 (1.3)            | 2 (1.9)                                                                                                   |       | 19 (0.8)                                                                                                                             |       |
| Elevation of bilirubin level, 1.5x higher                                                                                                       |          | 1 (0.3)                                                                                                                               | 4 (0.3)             | 3 (1.0)          | 2 (1.1)           | - (0.0)           | - (0.0)            | - (0.0)                                                                                                   |       | 10 (0.4)                                                                                                                             |       |

1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLI cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup>**

| Events                                                              | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2013) |                             |                         |                            |                          |                             | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(Jun 2013 - Nov 2013) | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(Jul 2009 - Nov 2013) |
|---------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------------------|----------------------------|--------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
|                                                                     |          | <u>Dronedaron</u><br>4,245                                                                                                            | <u>Amiodarone</u><br>10,582 | <u>Sotalol</u><br>3,491 | <u>Flecainide</u><br>3,019 | <u>Dofetilide</u><br>638 | <u>Propafenone</u><br>1,995 | <u>Total</u><br>2,781                                                                                     | <u>Total</u><br>23,970                                                                                                               |
|                                                                     |          | N (%)                                                                                                                                 | N (%)                       | N (%)                   | N (%)                      | N (%)                    | N (%)                       | N (%)                                                                                                     | N (%)                                                                                                                                |
| <b>Total<sup>5</sup></b>                                            |          | <b>138 (3.3)</b>                                                                                                                      | <b>424 (4.0)</b>            | <b>109 (3.1)</b>        | <b>50 (1.7)</b>            | <b>21 (3.3)</b>          | <b>44 (2.2)</b>             | <b>46 (1.7)</b>                                                                                           | <b>786 (3.3)</b>                                                                                                                     |
| <b>Interstitial Lung Disease<sup>6</sup></b>                        |          |                                                                                                                                       |                             |                         |                            |                          |                             |                                                                                                           |                                                                                                                                      |
| <u>ICD-9-CM Diagnoses</u>                                           |          |                                                                                                                                       |                             |                         |                            |                          |                             |                                                                                                           |                                                                                                                                      |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |          | 2 (1.4)                                                                                                                               | 3 (0.7)                     | 2 (1.8)                 | 2 (4.0)                    | - (0.0)                  | 1 (2.3)                     | 1 (2.2)                                                                                                   | 10 (1.3)                                                                                                                             |
| 515.xx Postinflammatory pulmonary fibrosis                          |          | 114 (82.6)                                                                                                                            | 328 (77.4)                  | 92 (84.4)               | 40 (80.0)                  | 17 (81.0)                | 38 (86.4)                   | 36 (78.3)                                                                                                 | 629 (80.0)                                                                                                                           |
| 516.3x Idiopathic fibrosing alveolitis                              |          | 16 (11.6)                                                                                                                             | 49 (11.6)                   | 8 (7.3)                 | 5 (10.0)                   | 5 (23.8)                 | 4 (9.1)                     | 5 (10.9)                                                                                                  | 87 (11.1)                                                                                                                            |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified   |          | 3 (2.2)                                                                                                                               | 3 (0.7)                     | 1 (0.9)                 | 1 (2.0)                    | - (0.0)                  | - (0.0)                     | 3 (6.5)                                                                                                   | 8 (1.0)                                                                                                                              |
| 516.31 Idiopathic pulmonary fibrosis                                |          | 5 (3.6)                                                                                                                               | 21 (5.0)                    | 1 (0.9)                 | 1 (2.0)                    | 3 (14.3)                 | 1 (2.3)                     | 1 (2.2)                                                                                                   | 32 (4.1)                                                                                                                             |
| 516.32 Idiopathic non-specific interstitial pneumonitis             |          | - (0.0)                                                                                                                               | - (0.0)                     | - (0.0)                 | - (0.0)                    | - (0.0)                  | - (0.0)                     | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.33 Acute interstitial pneumonitis                               |          | - (0.0)                                                                                                                               | 3 (0.7)                     | - (0.0)                 | - (0.0)                    | - (0.0)                  | - (0.0)                     | - (0.0)                                                                                                   | 3 (0.4)                                                                                                                              |
| 516.34 Respiratory bronchiolitis interstitial lung disease          |          | 1 (0.7)                                                                                                                               | 1 (0.2)                     | - (0.0)                 | - (0.0)                    | - (0.0)                  | - (0.0)                     | 1 (2.2)                                                                                                   | 2 (0.3)                                                                                                                              |
| 516.35 Idiopathic lymphoid interstitial pneumonia                   |          | - (0.0)                                                                                                                               | - (0.0)                     | - (0.0)                 | - (0.0)                    | - (0.0)                  | - (0.0)                     | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.36 Cryptogenic organizing pneumonia                             |          | - (0.0)                                                                                                                               | - (0.0)                     | - (0.0)                 | 1 (2.0)                    | - (0.0)                  | - (0.0)                     | - (0.0)                                                                                                   | 1 (0.1)                                                                                                                              |
| 516.37 Desquamative interstitial pneumonia                          |          | - (0.0)                                                                                                                               | - (0.0)                     | - (0.0)                 | - (0.0)                    | - (0.0)                  | - (0.0)                     | - (0.0)                                                                                                   | - (0.0)                                                                                                                              |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |          | 4 (2.9)                                                                                                                               | 29 (6.8)                    | 5 (4.6)                 | 1 (2.0)                    | - (0.0)                  | 3 (6.8)                     | 3 (6.5)                                                                                                   | 42 (5.3)                                                                                                                             |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |          | 6 (4.3)                                                                                                                               | 22 (5.2)                    | 4 (3.7)                 | 2 (4.0)                    | - (0.0)                  | - (0.0)                     | 1 (2.2)                                                                                                   | 34 (4.3)                                                                                                                             |

1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Dronedarone</b> |               | <b>Amiodarone</b> |               | <b>Sotalol</b> |               | <b>Flecainide</b> |               | <b>Dofetilide</b> |               | <b>Propafenone</b> |               | <b>Total</b>  |               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|-------------------|---------------|----------------|---------------|-------------------|---------------|-------------------|---------------|--------------------|---------------|---------------|---------------|
| <b>Patients</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           | <i>N</i>           | (%)           | <i>N</i>          | (%)           | <i>N</i>       | (%)           | <i>N</i>          | (%)           | <i>N</i>          | (%)           | <i>N</i>           | (%)           | <i>N</i>      | (%)           |
| <b>Total patients identified through end of current period, Jul 2009 - Nov 2013</b>                                                                                                                                                                                                                                                                                                                                                                       | <b>4,245</b>       | <b>(17.7)</b> | <b>10,582</b>     | <b>(44.1)</b> | <b>3,491</b>   | <b>(14.6)</b> | <b>3,019</b>      | <b>(12.6)</b> | <b>638</b>        | <b>(2.7)</b>  | <b>1,995</b>       | <b>(8.3)</b>  | <b>23,970</b> |               |
| <b>Age group, years</b>                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |               |                   |               |                |               |                   |               |                   |               |                    |               |               |               |
| < 18                                                                                                                                                                                                                                                                                                                                                                                                                                                      | -                  | (0.0)         | 2                 | (0.0)         | 4              | (0.1)         | 2                 | (0.1)         | -                 | (0.0)         | -                  | (0.0)         | 8             | (0.0)         |
| 18 - 24                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2                  | (0.0)         | 7                 | (0.1)         | 3              | (0.1)         | 21                | (0.7)         | 1                 | (0.2)         | 6                  | (0.3)         | 40            | (0.2)         |
| 25 - 34                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 24                 | (0.6)         | 30                | (0.3)         | 31             | (0.9)         | 78                | (2.6)         | 6                 | (0.9)         | 41                 | (2.1)         | 210           | (0.9)         |
| 35 - 44                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 134                | (3.2)         | 134               | (1.3)         | 113            | (3.2)         | 235               | (7.8)         | 22                | (3.4)         | 116                | (5.8)         | 754           | (3.1)         |
| 45 - 54                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 635                | (15.0)        | 822               | (7.8)         | 388            | (11.1)        | 636               | (21.1)        | 78                | (12.2)        | 366                | (18.3)        | 2,925         | (12.2)        |
| 55 - 64                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1,773              | (41.8)        | 2,593             | (24.5)        | 1,138          | (32.6)        | 1,247             | (41.3)        | 220               | (34.5)        | 786                | (39.4)        | 7,757         | (32.4)        |
| 65 - 74                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 869                | (20.5)        | 2,724             | (25.7)        | 855            | (24.5)        | 487               | (16.1)        | 177               | (27.7)        | 365                | (18.3)        | 5,477         | (22.8)        |
| 75 - 84                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 615                | (14.5)        | 2,941             | (27.8)        | 729            | (20.9)        | 257               | (8.5)         | 106               | (16.6)        | 245                | (12.3)        | 4,893         | (20.4)        |
| 85+                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 193                | (4.5)         | 1,329             | (12.6)        | 230            | (6.6)         | 56                | (1.9)         | 28                | (4.4)         | 70                 | (3.5)         | 1,906         | (8.0)         |
| <b>Age group, female, years</b>                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>1,431</b>       | <b>(33.7)</b> | <b>3,877</b>      | <b>(36.6)</b> | <b>1,397</b>   | <b>(40.0)</b> | <b>1,181</b>      | <b>(39.1)</b> | <b>206</b>        | <b>(32.3)</b> | <b>725</b>         | <b>(36.3)</b> | <b>8,817</b>  | <b>(36.8)</b> |
| < 18, female                                                                                                                                                                                                                                                                                                                                                                                                                                              | -                  | (0.0)         | 2                 | (0.1)         | 3              | (0.2)         | -                 | (0.0)         | -                 | (0.0)         | -                  | (0.0)         | 5             | (0.1)         |
| 18 - 24, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | -                  | (0.0)         | 3                 | (0.1)         | -              | (0.0)         | 5                 | (0.4)         | 1                 | (0.5)         | -                  | (0.0)         | 9             | (0.1)         |
| 25 - 34, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3                  | (0.2)         | 6                 | (0.2)         | 12             | (0.9)         | 19                | (1.6)         | 2                 | (1.0)         | 10                 | (1.4)         | 52            | (0.6)         |
| 35 - 44, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 23                 | (1.6)         | 25                | (0.6)         | 19             | (1.4)         | 60                | (5.1)         | 5                 | (2.4)         | 17                 | (2.3)         | 149           | (1.7)         |
| 45 - 54, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 127                | (8.9)         | 158               | (4.1)         | 100            | (7.2)         | 172               | (14.6)        | 15                | (7.3)         | 71                 | (9.8)         | 643           | (7.3)         |
| 55 - 64, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 497                | (34.7)        | 592               | (15.3)        | 341            | (24.4)        | 451               | (38.2)        | 60                | (29.1)        | 267                | (36.8)        | 2,208         | (25.0)        |
| 65 - 74, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 332                | (23.2)        | 916               | (23.6)        | 362            | (25.9)        | 250               | (21.2)        | 58                | (28.2)        | 176                | (24.3)        | 2,094         | (23.7)        |
| 75 - 84, female                                                                                                                                                                                                                                                                                                                                                                                                                                           | 313                | (21.9)        | 1,357             | (35.0)        | 400            | (28.6)        | 174               | (14.7)        | 48                | (23.3)        | 140                | (19.3)        | 2,432         | (27.6)        |
| 85+, female                                                                                                                                                                                                                                                                                                                                                                                                                                               | 136                | (9.5)         | 818               | (21.1)        | 160            | (11.5)        | 50                | (4.2)         | 17                | (8.3)         | 44                 | (6.1)         | 1,225         | (13.9)        |
| <b>Age group, male, years</b>                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>2,814</b>       | <b>(66.3)</b> | <b>6,705</b>      | <b>(63.4)</b> | <b>2,094</b>   | <b>(60.0)</b> | <b>1,838</b>      | <b>(60.9)</b> | <b>432</b>        | <b>(67.7)</b> | <b>1,270</b>       | <b>(63.7)</b> | <b>15,153</b> | <b>(63.2)</b> |
| < 18, male                                                                                                                                                                                                                                                                                                                                                                                                                                                | -                  | (0.0)         | -                 | (0.0)         | 1              | (0.0)         | 2                 | (0.1)         | -                 | (0.0)         | -                  | (0.0)         | 3             | (0.0)         |
| 18 - 24, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 2                  | (0.1)         | 4                 | (0.1)         | 3              | (0.1)         | 16                | (0.9)         | -                 | (0.0)         | 6                  | (0.5)         | 31            | (0.2)         |
| 25 - 34, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 21                 | (0.7)         | 24                | (0.4)         | 19             | (0.9)         | 59                | (3.2)         | 4                 | (0.9)         | 31                 | (2.4)         | 158           | (1.0)         |
| 35 - 44, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 111                | (3.9)         | 109               | (1.6)         | 94             | (4.5)         | 175               | (9.5)         | 17                | (3.9)         | 99                 | (7.8)         | 605           | (4.0)         |
| 45 - 54, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 508                | (18.1)        | 664               | (9.9)         | 288            | (13.8)        | 464               | (25.2)        | 63                | (14.6)        | 295                | (23.2)        | 2,282         | (15.1)        |
| 55 - 64, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1,276              | (45.3)        | 2,001             | (29.8)        | 797            | (38.1)        | 796               | (43.3)        | 160               | (37.0)        | 519                | (40.9)        | 5,549         | (36.6)        |
| 65 - 74, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 537                | (19.1)        | 1,808             | (27.0)        | 493            | (23.5)        | 237               | (12.9)        | 119               | (27.5)        | 189                | (14.9)        | 3,383         | (22.3)        |
| 75 - 84, male                                                                                                                                                                                                                                                                                                                                                                                                                                             | 302                | (10.7)        | 1,584             | (23.6)        | 329            | (15.7)        | 83                | (4.5)         | 58                | (13.4)        | 105                | (8.3)         | 2,461         | (16.2)        |
| 85+, male                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 57                 | (2.0)         | 511               | (7.6)         | 70             | (3.3)         | 6                 | (0.3)         | 11                | (2.5)         | 26                 | (2.0)         | 681           | (4.5)         |
| 1. This Table will be completed each quarter during the prospective count for fully insured patients only, for whom claims profiles can be shared externally outside of HealthCore, Inc.<br>2. Only the index study drug will be counted, therefore a patient is only counted once.<br>3. Eligibility criteria were reassessed for patients identified during the retrospective and prior prospective periods and only those still eligible are included. |                    |               |                   |               |                |               |                   |               |                   |               |                    |               |               |               |

# **Age Distribution of Index Users, By Cohort, Through End of Current Period (Jul 2009 - Nov 2013), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)**

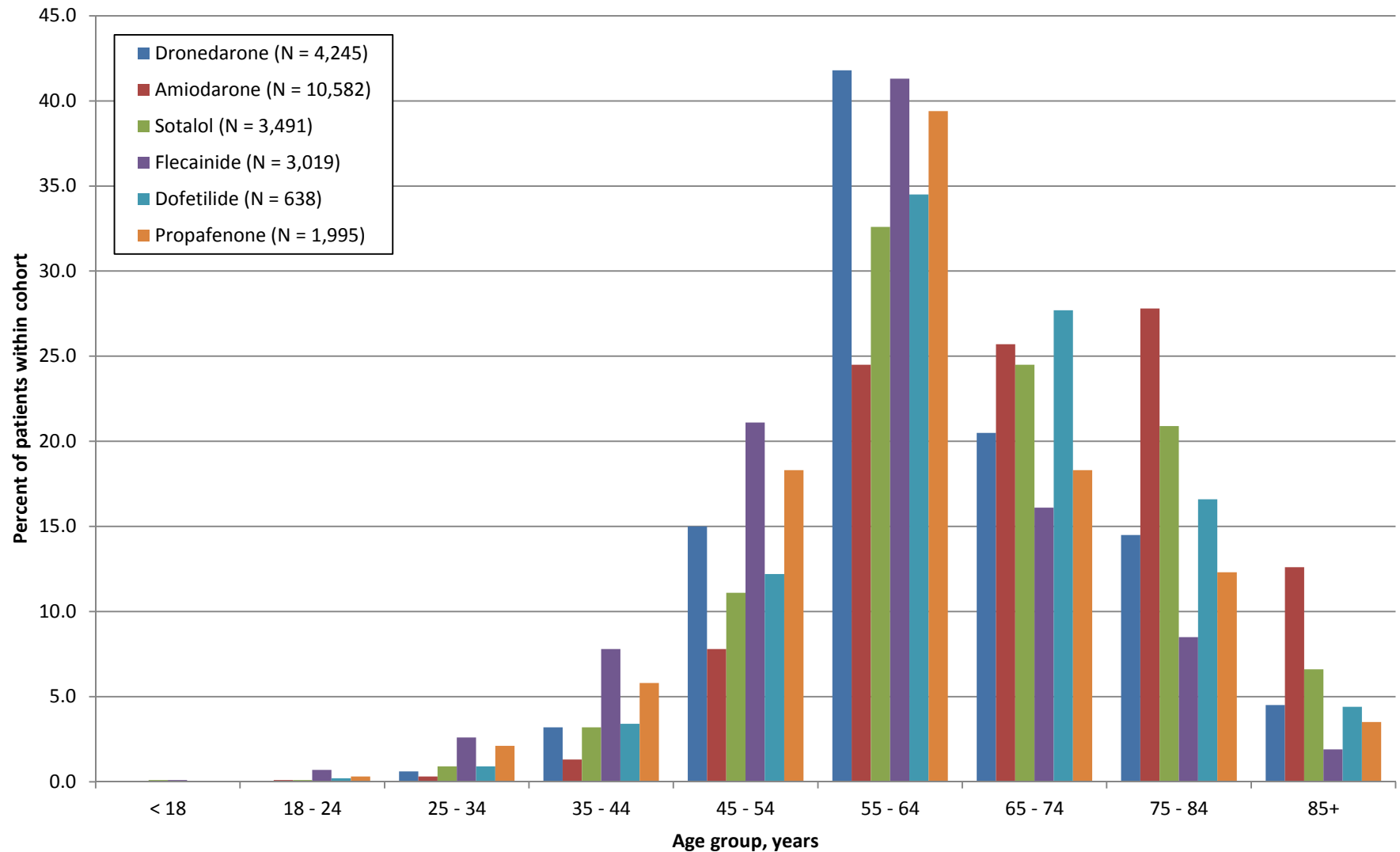


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Table 1B. Number of Patients with a Study Drug of Interest between 20 Jul 2009 and 31 Mar 2014, By Study Drug Cohort and Screening Criteria; HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

Table 2. Serious Liver Injury/Disease (SLD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

Table 4. Age Distribution of Index Users, By Gender and Cohort, Through End of Current Period (20 Jul 2009 - 31 Mar 2014), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

Figure 1. Age Distribution of Index Users, By Cohort, Through End of Current Period (20 Jul 2009 - 31 Mar 2014), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)

| Table 1A. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database <sup>SM</sup> (HIRD) <sup>1,2,3</sup>                                                                                                                                                                                                                                |             |        |            |        |         |        |            |        |            |        |             |        |        |         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------|------------|--------|---------|--------|------------|--------|------------|--------|-------------|--------|--------|---------|
| Patients                                                                                                                                                                                                                                                                                                                                                                                 | Dronedarone |        | Amiodarone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone |        | Total  |         |
|                                                                                                                                                                                                                                                                                                                                                                                          | N           | (%)    | N          | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N           | (%)    | N      | (%)     |
| Total patients identified through end of current period, 20 Jul 2009 - 31 Mar 2014 <sup>4</sup>                                                                                                                                                                                                                                                                                          | 5,718       | (12.7) | 21,960     | (48.9) | 6,911   | (15.4) | 5,539      | (12.3) | 993        | (2.2)  | 3,783       | (8.4)  | 44,904 | (100.0) |
| Patients identified with index dates prior to the current period, 20 Jul 2009 - 30 Nov 201 <sup>4</sup>                                                                                                                                                                                                                                                                                  | 5,517       | (96.5) | 20,502     | (93.4) | 6,479   | (93.7) | 5,187      | (93.6) | 924        | (93.1) | 3,575       | (94.5) | 42,184 | (93.9)  |
| New patients identified with index dates during the current period, 01 Dec 2013 - 31 Mar 2014                                                                                                                                                                                                                                                                                            | 201         | (3.5)  | 1,458      | (6.6)  | 432     | (6.3)  | 352        | (6.4)  | 69         | (6.9)  | 208         | (5.5)  | 2,720  | (6.1)   |
| 1. Among the HealthCore Integrated Research Database <sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population. |             |        |            |        |         |        |            |        |            |        |             |        |        |         |
| 2. Only the index study drug will be counted, therefore a patient is only counted once.                                                                                                                                                                                                                                                                                                  |             |        |            |        |         |        |            |        |            |        |             |        |        |         |
| 3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.                                                                                                                                                                                                                               |             |        |            |        |         |        |            |        |            |        |             |        |        |         |
| 4. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period.                                                                                                                                                                                                                  |             |        |            |        |         |        |            |        |            |        |             |        |        |         |



**Table 18. Number of Patients with a Study Drug of Interest between 20 Jul 2009 and 31 Mar 2014, By Study Drug Cohort and Screening Criteria; HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1</sup>**

| Screening Description                                                         | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Total <sup>2</sup> |       |
|-------------------------------------------------------------------------------|-------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|--------------------|-------|
|                                                                               | N           | (%)   | N          | (%)   | N       | (%)   | N          | (%)   | N          | (%)   | N           | (%)   | N                  | (%)   |
| Assign the first study drug as the cohort                                     | 9,039       | (100) | 53,143     | (100) | 24,297  | (100) | 19,108     | (100) | 3,182      | (100) | 12,203      | (100) | 120,926            | (100) |
| Less patients without 365 days of eligibility prior to index date             | 2,687       | (30)  | 13,017     | (24)  | 7,822   | (32)  | 6,364      | (33)  | 1,151      | (36)  | 3,775       | (31)  | 34,802             | (29)  |
| Less patients without AF in the year prior to index date                      | 574         | (6)   | 9,483      | (18)  | 3,582   | (15)  | 3,579      | (19)  | 98         | (3)   | 1,678       | (14)  | 18,987             | (16)  |
| Less patients with the index drug in the year prior to index date             | 0           | (0)   | 8,163      | (15)  | 5,879   | (24)  | 3,566      | (19)  | 921        | (29)  | 2,915       | (24)  | 21,436             | (18)  |
| Less patients with multiple study drugs on index date                         | 3           | (0)   | 12         | (0)   | 8       | (0)   | 3          | (0)   | 1          | (0)   | 7           | (0)   | 17                 | (0)   |
| Less patients with date of death preceding index date                         | 8           | (0)   | 11         | (0)   | 5       | (0)   | 1          | (0)   | 2          | (0)   | 2           | (0)   | 29                 | (0)   |
| Less patients below 18 years old on index date <sup>3</sup>                   | 1           | (0)   | 2          | (0)   | 3       | (0)   | 9          | (0)   | 0          | (0)   | 1           | (0)   | 16                 | (0)   |
| Less patients with cancer or organ transplant in baseline period <sup>3</sup> | 41          | (0)   | 458        | (1)   | 74      | (0)   | 29         | (0)   | 11         | (0)   | 36          | (0)   | 649                | (1)   |
| Less patients with HIV in baseline period <sup>3</sup>                        | 6           | (0)   | 16         | (0)   | 5       | (0)   | 7          | (0)   | 2          | (0)   | 1           | (0)   | 37                 | (0)   |
| Less patients with pregnancy codes prior and/or post index date <sup>3</sup>  | 1           | (0)   | 21         | (0)   | 8       | (0)   | 11         | (0)   | 3          | (0)   | 5           | (0)   | 49                 | (0)   |
| Remaining patients prior to screening for Outcome Cohorts                     | 5,718       | (63)  | 21,960     | (41)  | 6,911   | (28)  | 5,539      | (29)  | 993        | (31)  | 3,783       | (31)  | 44,904             | (37)  |

**Serious Liver Injury/Disease (SLD) - Prior SLD Screening<sup>3</sup>**

|                                                                  | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             | Total         |             |
|------------------------------------------------------------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
| Remaining patients prior to identifying outcome analysis cohorts | 5,718        | (63)        | 21,960        | (41)        | 6,911        | (28)        | 5,539        | (29)        | 993        | (31)        | 3,783        | (31)        | 44,904        | (37)        |
| Less patients with SLD in baseline period                        | 261          | (3)         | 1,523         | (3)         | 358          | (1)         | 201          | (1)         | 44         | (1)         | 143          | (1)         | 2,530         | (2)         |
| <b>Study Cohorts for SLD Outcome Analysis</b>                    | <b>5,457</b> | <b>(60)</b> | <b>20,437</b> | <b>(38)</b> | <b>6,553</b> | <b>(27)</b> | <b>5,338</b> | <b>(28)</b> | <b>949</b> | <b>(30)</b> | <b>3,640</b> | <b>(30)</b> | <b>42,374</b> | <b>(35)</b> |

**Interstitial Lung Disease (ILD) - Prior ILD Screening<sup>3</sup>**

|                                                                  | Dronedarone  |             | Amiodarone    |             | Sotalol      |             | Flecainide   |             | Dofetilide |             | Propafenone  |             | Total         |             |
|------------------------------------------------------------------|--------------|-------------|---------------|-------------|--------------|-------------|--------------|-------------|------------|-------------|--------------|-------------|---------------|-------------|
| Remaining patients prior to identifying outcome analysis cohorts | 5,718        | (63)        | 21,960        | (41)        | 6,911        | (28)        | 5,539        | (29)        | 993        | (31)        | 3,783        | (31)        | 44,904        | (37)        |
| Less patients with ILD in baseline period                        | 265          | (3)         | 1,853         | (3)         | 354          | (1)         | 137          | (1)         | 60         | (2)         | 121          | (1)         | 2,790         | (2)         |
| <b>Study Cohorts for ILD Outcome Analysis</b>                    | <b>5,453</b> | <b>(60)</b> | <b>20,107</b> | <b>(38)</b> | <b>6,557</b> | <b>(27)</b> | <b>5,402</b> | <b>(28)</b> | <b>933</b> | <b>(29)</b> | <b>3,662</b> | <b>(30)</b> | <b>42,114</b> | <b>(35)</b> |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc.<sup>4</sup> The Epidemiology Study will be conducted using this patient population. Only the index study drug will be counted, therefore a patient is only counted once. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period. Percentages are reported as the number of patients identified divided by the number of patients with the first study drug assigned as the cohort.

2. Patients allowed to contribute to multiple index drug columns until excluding for multiple study drugs on index date. Blue-highlighted Total counts are unique patients and not the sum of counts across drug columns.

3. Additional screening to reflect Epidemiology Study Protocol.

4. Per study-specific exemption recently granted by HealthCore leadership in Oct 2014 to allow the inclusion of administrative services opt-in patients for this study. Such patients were excluded in all previous accrual reports.

**Table 2. Serious Liver Injury/Disease (SLD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup>**

| Events                                                                   |  | Cumulative SLD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 31 Mar 2014) |        |            |        |         |        |            |        |            |        | Total SLD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(01 Dec 2013 - 31 Mar 2014) |        | Cumulative Total SLD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 31 Mar 2014) |        |       |        |
|--------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------------------------------|--------|------------|--------|---------|--------|------------|--------|------------|--------|-----------------------------------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------|--------|-------|--------|
|                                                                          |  | Dronedarone                                                                                                                                 |        | Amiodarone |        | Sotalol |        | Flecainide |        | Dofetilide |        | Propafenone                                                                                                     |        | Total                                                                                                                                      |        |       |        |
|                                                                          |  | 5,457                                                                                                                                       | 20,437 | 6,553      | 5,338  | 949     | 3,640  | 2,558      | 42,374 |            |        |                                                                                                                 |        |                                                                                                                                            |        |       |        |
| Patients                                                                 |  | N                                                                                                                                           | (%)    | N          | (%)    | N       | (%)    | N          | (%)    | N          | (%)    | N                                                                                                               | (%)    | N                                                                                                                                          | (%)    |       |        |
| Total with at least one occurrence of an SLD code <sup>5</sup>           |  | 243                                                                                                                                         | (4.5)  | 1,169      | (5.7)  | 295     | (4.5)  | 151        | (2.8)  | 45         | (4.7)  | 158                                                                                                             | (4.3)  | 24                                                                                                                                         | (0.9)  | 2,061 | (4.9)  |
| Serious Liver Injury/Disease <sup>6</sup>                                |  |                                                                                                                                             |        |            |        |         |        |            |        |            |        |                                                                                                                 |        |                                                                                                                                            |        |       |        |
| ICD-9-CM Diagnoses                                                       |  |                                                                                                                                             |        |            |        |         |        |            |        |            |        |                                                                                                                 |        |                                                                                                                                            |        |       |        |
| 277.4x Disorders of bilirubin excretion                                  |  | 6                                                                                                                                           | (2.5)  | 27         | (2.3)  | 8       | (2.7)  | 4          | (2.6)  | 1          | (2.2)  | 3                                                                                                               | (1.9)  | -                                                                                                                                          | (0.0)  | 49    | (2.4)  |
| 570.xx Acute and subacute necrosis of liver                              |  | 16                                                                                                                                          | (6.6)  | 95         | (8.1)  | 18      | (6.1)  | 6          | (4.0)  | 2          | (4.4)  | 3                                                                                                               | (1.9)  | 3                                                                                                                                          | (12.5) | 140   | (6.8)  |
| 571.5x Cirrhosis of liver without mention of alcohol                     |  | 14                                                                                                                                          | (5.8)  | 73         | (6.2)  | 18      | (6.1)  | 5          | (3.3)  | 4          | (8.9)  | 8                                                                                                               | (5.1)  | 2                                                                                                                                          | (8.3)  | 122   | (5.9)  |
| 572.2x Hepatic coma                                                      |  | 1                                                                                                                                           | (0.4)  | 16         | (1.4)  | 3       | (1.0)  | -          | (0.0)  | 1          | (2.2)  | 2                                                                                                               | (1.3)  | -                                                                                                                                          | (0.0)  | 23    | (1.1)  |
| 572.4x Hepatorenal syndrome                                              |  | -                                                                                                                                           | (0.0)  | 4          | (0.3)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 4     | (0.2)  |
| 572.8x Other sequelae of chronic liver disease                           |  | -                                                                                                                                           | (0.0)  | 14         | (1.2)  | 5       | (1.7)  | 3          | (2.0)  | -          | (0.0)  | 3                                                                                                               | (1.9)  | -                                                                                                                                          | (0.0)  | 25    | (1.2)  |
| 573.0x Chronic passive congestion of liver                               |  | 2                                                                                                                                           | (0.8)  | 13         | (1.1)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | 2                                                                                                               | (1.3)  | -                                                                                                                                          | (0.0)  | 18    | (0.9)  |
| 573.3x Hepatitis, unspecified                                            |  | 18                                                                                                                                          | (7.4)  | 108        | (9.2)  | 15      | (5.1)  | 10         | (6.6)  | 1          | (2.2)  | 9                                                                                                               | (5.7)  | 4                                                                                                                                          | (16.7) | 161   | (7.8)  |
| 573.8x Other specified disorders of liver                                |  | 78                                                                                                                                          | (32.1) | 313        | (26.8) | 91      | (30.8) | 64         | (42.4) | 18         | (40.0) | 63                                                                                                              | (39.9) | 6                                                                                                                                          | (25.0) | 627   | (30.4) |
| 573.9x Unspecified disorder of liver                                     |  | 30                                                                                                                                          | (12.3) | 125        | (10.7) | 43      | (14.6) | 17         | (11.3) | 4          | (8.9)  | 20                                                                                                              | (12.7) | 3                                                                                                                                          | (12.5) | 239   | (11.6) |
| 782.4x Jaundice, unspecified                                             |  | 16                                                                                                                                          | (6.6)  | 93         | (8.0)  | 20      | (6.8)  | 9          | (6.0)  | 4          | (8.9)  | 11                                                                                                              | (7.0)  | 2                                                                                                                                          | (8.3)  | 153   | (7.4)  |
| 794.8x Nonspecific abnormal results of liver function test               |  | 61                                                                                                                                          | (25.1) | 311        | (26.6) | 79      | (26.8) | 36         | (23.8) | 12         | (26.7) | 40                                                                                                              | (25.3) | 6                                                                                                                                          | (25.0) | 539   | (26.2) |
| V42.7x Liver transplant status                                           |  | 1                                                                                                                                           | (0.4)  | 1          | (0.1)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 2     | (0.1)  |
| ICD-9-CM Procedures                                                      |  |                                                                                                                                             |        |            |        |         |        |            |        |            |        |                                                                                                                 |        |                                                                                                                                            |        |       |        |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                     |  | 2                                                                                                                                           | (0.8)  | 14         | (1.2)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | 2                                                                                                               | (1.3)  | 1                                                                                                                                          | (4.2)  | 19    | (0.9)  |
| 50.12 Open biopsy of liver                                               |  | -                                                                                                                                           | (0.0)  | 1          | (0.1)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 2     | (0.1)  |
| 50.13 Transjugular liver biopsy                                          |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| 50.14 Laparoscopic liver biopsy                                          |  | -                                                                                                                                           | (0.0)  | 2          | (0.2)  | 3       | (1.0)  | -          | (0.0)  | -          | (0.0)  | 1                                                                                                               | (0.6)  | -                                                                                                                                          | (0.0)  | 6     | (0.3)  |
| 50.5x Liver transplant                                                   |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| 50.51 Auxiliary liver transplant                                         |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| 50.59 Other transplant of liver                                          |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| 50.91 Percutaneous aspiration of liver                                   |  | -                                                                                                                                           | (0.0)  | 1          | (0.1)  | 2       | (0.7)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 3     | (0.1)  |
| CPT Procedures                                                           |  |                                                                                                                                             |        |            |        |         |        |            |        |            |        |                                                                                                                 |        |                                                                                                                                            |        |       |        |
| CPT 47000 Biopsy of liver, needle; percutaneous                          |  | 1                                                                                                                                           | (0.4)  | 7          | (0.6)  | 1       | (0.3)  | 4          | (2.6)  | -          | (0.0)  | 5                                                                                                               | (3.2)  | -                                                                                                                                          | (0.0)  | 18    | (0.9)  |
| CPT 47001 Biopsy of liver, needle; done at time of other major procedure |  | 1                                                                                                                                           | (0.4)  | 6          | (0.5)  | 1       | (0.3)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 8     | (0.4)  |
| CPT 47100 Biopsy of liver, wedge                                         |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | 2                                                                                                               | (1.3)  | -                                                                                                                                          | (0.0)  | 2     | (0.1)  |
| CPT 47135 Liver allotransplantation; orthotopic, partial or whole        |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| CPT 47136 Liver allotransplantation; heterotopic, partial or whole       |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |
| CPT 78205 Liver imaging (SPECT)                                          |  | -                                                                                                                                           | (0.0)  | 2          | (0.2)  | -       | (0.0)  | 1          | (0.7)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | 3     | (0.1)  |
| CPT 78206 Liver imaging (SPECT); with vascular flow                      |  | -                                                                                                                                           | (0.0)  | -          | (0.0)  | -       | (0.0)  | -          | (0.0)  | -          | (0.0)  | -                                                                                                               | (0.0)  | -                                                                                                                                          | (0.0)  | -     | (0.0)  |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population. For serious liver injury/disease (SLD) counts, patients with SLD in the baseline period were excluded.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup>**

| Events                                                               | Patients | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 31 Mar 2014) |              |              |              |            |              |            |              |            |              | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(01 Dec 2013 - 31 Mar 2014) |              | Cumulative Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 31 Mar 2014) |              |
|----------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|--------------|------------|--------------|------------|--------------|------------|--------------|-----------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                      |          | Dronedarone                                                                                                                                 |              | Amiodarone   |              | Sotalol    |              | Flecainide |              | Dofetilide |              | Propafenone                                                                                                     |              | Total                                                                                                                                      |              |
|                                                                      |          | N                                                                                                                                           | (%)          | N            | (%)          | N          | (%)          | N          | (%)          | N          | (%)          | N                                                                                                               | (%)          | N                                                                                                                                          | (%)          |
| <b>Total with at least one occurrence of an ILD code<sup>5</sup></b> |          | <b>199</b>                                                                                                                                  | <b>(3.6)</b> | <b>1,147</b> | <b>(5.7)</b> | <b>228</b> | <b>(3.5)</b> | <b>93</b>  | <b>(1.7)</b> | <b>32</b>  | <b>(3.4)</b> | <b>96</b>                                                                                                       | <b>(2.6)</b> | <b>28</b>                                                                                                                                  | <b>(1.1)</b> |
| Interstitial Lung Disease <sup>6</sup>                               |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                            |              |
| ICD-9-CM Diagnoses                                                   |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                            |              |
| 495.9x Unspecified allergic alveolitis and pneumonitis               |          | 1                                                                                                                                           | (0.5)        | 5            | (0.4)        | 3          | (1.3)        | 1          | (1.1)        | -          | (0.0)        | 1                                                                                                               | (1.0)        | 1                                                                                                                                          | (3.6)        |
| 515.xx Postinflammatory pulmonary fibrosis                           |          | 110                                                                                                                                         | (55.3)       | 556          | (48.5)       | 138        | (60.5)       | 45         | (48.4)       | 14         | (43.8)       | 57                                                                                                              | (59.4)       | 13                                                                                                                                         | (46.4)       |
| 516.3x Idiopathic fibrosing alveolitis                               |          | 8                                                                                                                                           | (4.0)        | 49           | (4.3)        | 11         | (4.8)        | 8          | (8.6)        | 2          | (6.3)        | 1                                                                                                               | (1.0)        | -                                                                                                                                          | (0.0)        |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified    |          | 3                                                                                                                                           | (1.5)        | 6            | (0.5)        | 3          | (1.3)        | 2          | (2.2)        | -          | (0.0)        | 1                                                                                                               | (1.0)        | -                                                                                                                                          | (0.0)        |
| 516.31 Idiopathic pulmonary fibrosis                                 |          | 1                                                                                                                                           | (0.5)        | 16           | (1.4)        | 3          | (1.3)        | 1          | (1.1)        | 2          | (6.3)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.32 Idiopathic non-specific interstitial pneumonitis              |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.33 Acute interstitial pneumonitis                                |          | -                                                                                                                                           | (0.0)        | 2            | (0.2)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.34 Respiratory bronchiolitis interstitial lung disease           |          | -                                                                                                                                           | (0.0)        | 2            | (0.2)        | -          | (0.0)        | 1          | (1.1)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.35 Idiopathic lymphoid interstitial pneumonia                    |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.36 Cryptogenic organizing pneumonia                              |          | -                                                                                                                                           | (0.0)        | 1            | (0.1)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.37 Desquamative interstitial pneumonia                           |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                          | (0.0)        |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies  |          | 4                                                                                                                                           | (2.0)        | 41           | (3.6)        | 4          | (1.8)        | 4          | (4.3)        | -          | (0.0)        | 4                                                                                                               | (4.2)        | 1                                                                                                                                          | (3.6)        |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy        |          | 9                                                                                                                                           | (4.5)        | 31           | (2.7)        | 7          | (3.1)        | 4          | (4.3)        | 1          | (3.1)        | 2                                                                                                               | (2.1)        | -                                                                                                                                          | (0.0)        |
| 518.82 Adult respiratory distress syndrome                           |          | 69                                                                                                                                          | (34.7)       | 484          | (42.2)       | 73         | (32.0)       | 33         | (35.5)       | 15         | (46.9)       | 32                                                                                                              | (33.3)       | 13                                                                                                                                         | (46.4)       |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population. For interstitial lung disease (ILD) counts, patients with ILD in the baseline period were excluded.

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6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

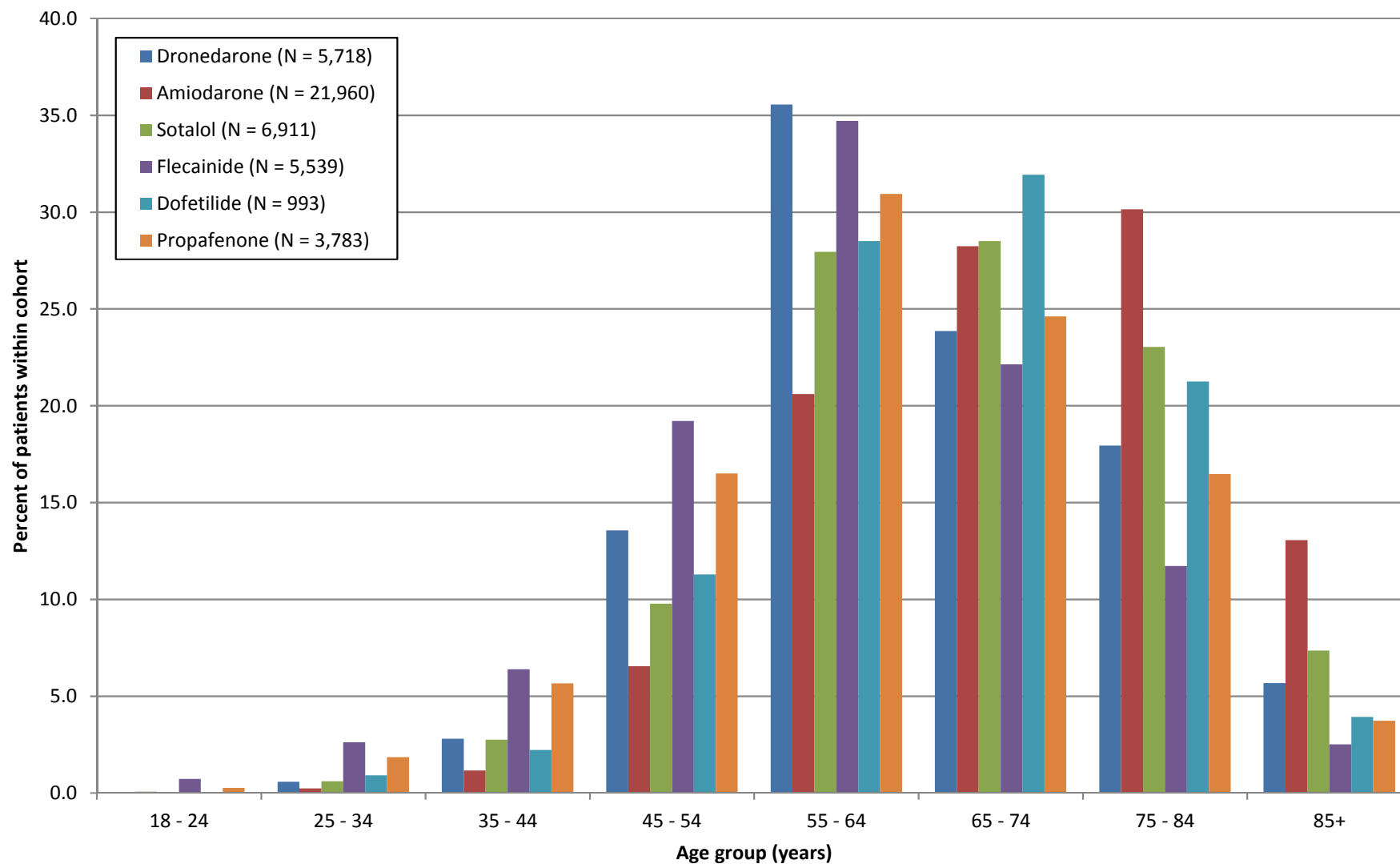
|                                                                                           | <b>Dronedarone</b> |               | <b>Amiodarone</b> |               | <b>Sotalol</b> |               | <b>Flecainide</b> |               | <b>Dofetilide</b> |              | <b>Propafenone</b> |              | <b>Total</b>  |            |
|-------------------------------------------------------------------------------------------|--------------------|---------------|-------------------|---------------|----------------|---------------|-------------------|---------------|-------------------|--------------|--------------------|--------------|---------------|------------|
| <b>Patients</b>                                                                           | <i>N</i>           | <i>(%)</i>    | <i>N</i>          | <i>(%)</i>    | <i>N</i>       | <i>(%)</i>    | <i>N</i>          | <i>(%)</i>    | <i>N</i>          | <i>(%)</i>   | <i>N</i>           | <i>(%)</i>   | <i>N</i>      | <i>(%)</i> |
| <b>Total patients identified through end of current period, 20 Jul 2009 - 31 Mar 2014</b> | <b>5,718</b>       | <b>(12.7)</b> | <b>21,960</b>     | <b>(48.9)</b> | <b>6,911</b>   | <b>(15.4)</b> | <b>5,539</b>      | <b>(12.3)</b> | <b>993</b>        | <b>(2.2)</b> | <b>3,783</b>       | <b>(8.4)</b> | <b>44,904</b> |            |
| <b>Age group (years)</b>                                                                  |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |            |
| 18 - 24                                                                                   | 3                  | (0.1)         | 13                | (0.1)         | 3              | (0.0)         | 40                | (0.7)         | -                 | (0.0)        | 10                 | (0.3)        | 69            | (0.2)      |
| 25 - 34                                                                                   | 33                 | (0.6)         | 52                | (0.2)         | 42             | (0.6)         | 145               | (2.6)         | 9                 | (0.9)        | 70                 | (1.9)        | 351           | (0.8)      |
| 35 - 44                                                                                   | 160                | (2.8)         | 254               | (1.2)         | 190            | (2.7)         | 354               | (6.4)         | 22                | (2.2)        | 214                | (5.7)        | 1,194         | (2.7)      |
| 45 - 54                                                                                   | 775                | (13.6)        | 1,436             | (6.5)         | 675            | (9.8)         | 1,064             | (19.2)        | 112               | (11.3)       | 624                | (16.5)       | 4,686         | (10.4)     |
| 55 - 64                                                                                   | 2,033              | (35.6)        | 4,522             | (20.6)        | 1,931          | (27.9)        | 1,922             | (34.7)        | 283               | (28.5)       | 1,170              | (30.9)       | 11,861        | (26.4)     |
| 65 - 74                                                                                   | 1,364              | (23.9)        | 6,199             | (28.2)        | 1,970          | (28.5)        | 1,226             | (22.1)        | 317               | (31.9)       | 931                | (24.6)       | 12,007        | (26.7)     |
| 75 - 84                                                                                   | 1,026              | (17.9)        | 6,618             | (30.1)        | 1,592          | (23.0)        | 649               | (11.7)        | 211               | (21.2)       | 623                | (16.5)       | 10,719        | (23.9)     |
| 85+                                                                                       | 324                | (5.7)         | 2,866             | (13.1)        | 508            | (7.4)         | 139               | (2.5)         | 39                | (3.9)        | 141                | (3.7)        | 4,017         | (8.9)      |
| <b>Age group, female (years)</b>                                                          |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |            |
| 18 - 24, female                                                                           | 2                  | (0.1)         | 4                 | (0.0)         | 1              | (0.0)         | 4                 | (0.2)         | -                 | (0.0)        | 3                  | (0.2)        | 14            | (0.1)      |
| 25 - 34, female                                                                           | 5                  | (0.2)         | 8                 | (0.1)         | 8              | (0.3)         | 30                | (1.3)         | 1                 | (0.3)        | 10                 | (0.7)        | 62            | (0.4)      |
| 35 - 44, female                                                                           | 33                 | (1.6)         | 39                | (0.5)         | 27             | (0.9)         | 95                | (4.0)         | 4                 | (1.2)        | 37                 | (2.4)        | 235           | (1.3)      |
| 45 - 54, female                                                                           | 174                | (8.4)         | 291               | (3.5)         | 190            | (6.6)         | 340               | (14.4)        | 22                | (6.9)        | 138                | (9.1)        | 1,155         | (6.6)      |
| 55 - 64, female                                                                           | 616                | (29.7)        | 1,069             | (12.9)        | 595            | (20.6)        | 741               | (31.4)        | 73                | (22.7)       | 410                | (26.9)       | 3,504         | (20.1)     |
| 65 - 74, female                                                                           | 519                | (25.0)        | 2,056             | (24.8)        | 842            | (29.2)        | 614               | (26.0)        | 101               | (31.5)       | 452                | (29.7)       | 4,584         | (26.2)     |
| 75 - 84, female                                                                           | 518                | (25.0)        | 3,065             | (36.9)        | 877            | (30.4)        | 429               | (18.2)        | 93                | (29.0)       | 376                | (24.7)       | 5,358         | (30.7)     |
| 85+, female                                                                               | 208                | (10.0)        | 1,772             | (21.3)        | 342            | (11.9)        | 109               | (4.6)         | 27                | (8.4)        | 97                 | (6.4)        | 2,555         | (14.6)     |
| <b>Age group, male (years)</b>                                                            |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |            |
| 18 - 24, male                                                                             | 1                  | (0.0)         | 9                 | (0.1)         | 2              | (0.0)         | 36                | (1.1)         | -                 | (0.0)        | 7                  | (0.3)        | 55            | (0.2)      |
| 25 - 34, male                                                                             | 28                 | (0.8)         | 44                | (0.3)         | 34             | (0.8)         | 115               | (3.6)         | 8                 | (1.2)        | 60                 | (2.7)        | 289           | (1.1)      |
| 35 - 44, male                                                                             | 127                | (3.5)         | 215               | (1.6)         | 163            | (4.0)         | 259               | (8.2)         | 18                | (2.7)        | 177                | (7.8)        | 959           | (3.5)      |
| 45 - 54, male                                                                             | 601                | (16.5)        | 1,145             | (8.4)         | 485            | (12.0)        | 724               | (22.8)        | 90                | (13.4)       | 486                | (21.5)       | 3,531         | (12.9)     |
| 55 - 64, male                                                                             | 1,417              | (38.9)        | 3,453             | (25.3)        | 1,336          | (33.2)        | 1,181             | (37.2)        | 210               | (31.3)       | 760                | (33.6)       | 8,357         | (30.5)     |
| 65 - 74, male                                                                             | 845                | (23.2)        | 4,143             | (30.3)        | 1,128          | (28.0)        | 612               | (19.3)        | 216               | (32.1)       | 479                | (21.2)       | 7,423         | (27.1)     |
| 75 - 84, male                                                                             | 508                | (13.9)        | 3,553             | (26.0)        | 715            | (17.7)        | 220               | (6.9)         | 118               | (17.6)       | 247                | (10.9)       | 5,361         | (19.5)     |
| 85+, male                                                                                 | 116                | (3.2)         | 1,094             | (8.0)         | 166            | (4.1)         | 30                | (0.9)         | 12                | (1.8)        | 44                 | (1.9)        | 1,462         | (5.3)      |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population.

2. Only the index study drug will be counted, therefore a patient is only counted once.

3. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period. Patients with serious liver injury/disease (SLD) or interstitial lung disease (ILD) in the baseline period were not excluded.

**Age Distribution of Index Users, By Cohort,  
Through End of Current Period (20 Jul 2009 - 31 Mar 2014),  
HealthCore Integrated Research Database<sup>SM</sup> (HIRD)**



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| <b>Table 1A. New Index Dronedarone and Comparator User Counts (Patient-Level), HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                           |               |                          |               |                       |               |                          |               |                          |                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------|--------------------------|---------------|-----------------------|---------------|--------------------------|---------------|--------------------------|--------------------|
| <b>Patients</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b><u>Dronedarone</u></b> |               | <b><u>Amiodarone</u></b> |               | <b><u>Sotalol</u></b> |               | <b><u>Flecainide</u></b> |               | <b><u>Dofetilide</u></b> |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <i>N</i>                  | <i>(%)</i>    | <i>N</i>                 | <i>(%)</i>    | <i>N</i>              | <i>(%)</i>    | <i>N</i>                 | <i>(%)</i>    | <i>N</i>                 | <i>(%)</i>         |
| <b>Total patients identified through end of current period, 20 Jul 2009 - 31 Mar 2014<sup>4</sup></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>5,699</b>              | <b>(12.7)</b> | <b>21,903</b>            | <b>(48.9)</b> | <b>6,905</b>          | <b>(15.4)</b> | <b>5,532</b>             | <b>(12.3)</b> | <b>992</b>               | <b>(2.2)</b>       |
| Patients identified with index dates prior to the current period, 20 Jul 2009 - 30 Nov 2013 <sup>4</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 5,497                     | (96.5)        | 20,448                   | (93.4)        | 6,474                 | (93.8)        | 5,178                    | (93.6)        | 923                      | (93.0)             |
| New patients identified with index dates during the current period, 01 Dec 2013 - 31 Mar 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 202                       | (3.5)         | 1,455                    | (6.6)         | 431                   | (6.2)         | 354                      | (6.4)         | 69                       | (7.0)              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |               |                          |               |                       |               |                          |               | 207                      | (5.5)              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                           |               |                          |               |                       |               |                          |               |                          | <b>2,718 (6.1)</b> |
| <p>1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population.</p> <p>2. Only the index study drug will be counted, therefore a patient is only counted once.</p> <p>3. Percentages are reported as the number of patients identified in the cohort and specified period divided by the total number of patients in the cohort.</p> <p>4. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period.</p> |                           |               |                          |               |                       |               |                          |               |                          |                    |

| Table 1B. Number of Patients with a Study Drug of Interest between 20 Jul 2009 and 31 Mar 2014, By Study Drug Cohort and Screening Criteria; HealthCore Integrated Research Database <sup>SM</sup> (HIRD) <sup>1</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------|------------|-------|---------|-------|------------|-------|------------|-------|-------------|-------|--------------------|-------|
| Screening Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Total <sup>2</sup> |       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | N           | (%)   | N          | (%)   | N       | (%)   | N          | (%)   | N          | (%)   | N           | (%)   | N                  | (%)   |
| Assign the first study drug as the cohort                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 9,025       | (100) | 53,042     | (100) | 24,297  | (100) | 19,093     | (100) | 3,179      | (100) | 12,193      | (100) | 120,783            | (100) |
| Less patients without 365 days of eligibility prior to index date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 2,695       | (30)  | 13,045     | (25)  | 7,845   | (32)  | 6,379      | (33)  | 1,151      | (36)  | 3,778       | (31)  | 34,879             | (29)  |
| Less patients without AF in the year prior to index date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 572         | (6)   | 9,456      | (18)  | 3,573   | (15)  | 3,568      | (19)  | 98         | (3)   | 1,677       | (14)  | 18,937             | (16)  |
| Less patients with the index drug in the year prior to index date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 0           | (0)   | 8,115      | (15)  | 5,870   | (24)  | 3,554      | (19)  | 919        | (29)  | 2,909       | (24)  | 21,359             | (18)  |
| Less patients with multiple study drugs on index date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3           | (0)   | 12         | (0)   | 8       | (0)   | 3          | (0)   | 1          | (0)   | 7           | (0)   | 17                 | (0)   |
| Less patients with date of death preceding index date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 7           | (0)   | 12         | (0)   | 5       | (0)   | 1          | (0)   | 2          | (0)   | 2           | (0)   | 29                 | (0)   |
| Less patients below 18 years old on index date <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 2           | (0)   | 2          | (0)   | 3       | (0)   | 9          | (0)   | 0          | (0)   | 1           | (0)   | 17                 | (0)   |
| Less patients with cancer or organ transplant in baseline period <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 40          | (0)   | 460        | (1)   | 74      | (0)   | 29         | (0)   | 11         | (0)   | 36          | (0)   | 650                | (1)   |
| Less patients with HIV in baseline period <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 6           | (0)   | 16         | (0)   | 5       | (0)   | 7          | (0)   | 2          | (0)   | 1           | (0)   | 37                 | (0)   |
| Less patients with pregnancy codes prior and/or post index date <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1           | (0)   | 21         | (0)   | 9       | (0)   | 11         | (0)   | 3          | (0)   | 5           | (0)   | 50                 | (0)   |
| Remaining patients prior to screening for Outcome Cohorts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 5,699       | (63)  | 21,903     | (41)  | 6,905   | (28)  | 5,532      | (29)  | 992        | (31)  | 3,777       | (31)  | 44,808             | (37)  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
| Serious Liver Injury/Disease (SLD) - Prior SLD Screening <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Total              |       |
| Remaining patients prior to identifying outcome analysis cohorts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 5,699       | (63)  | 21,903     | (41)  | 6,905   | (28)  | 5,532      | (29)  | 992        | (31)  | 3,777       | (31)  | 44,808             | (37)  |
| Less patients with SLD in baseline period                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 262         | (3)   | 1,518      | (3)   | 359     | (1)   | 200        | (1)   | 43         | (1)   | 143         | (1)   | 2,525              | (2)   |
| Study Cohorts for SLD Outcome Analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5,437       | (60)  | 20,385     | (38)  | 6,546   | (27)  | 5,332      | (28)  | 949        | (30)  | 3,634       | (30)  | 42,283             | (35)  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
| Interstitial Lung Disease (ILD) - Prior ILD Screening <sup>3</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Dronedarone |       | Amiodarone |       | Sotalol |       | Flecainide |       | Dofetilide |       | Propafenone |       | Total              |       |
| Remaining patients prior to identifying outcome analysis cohorts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 5,699       | (63)  | 21,903     | (41)  | 6,905   | (28)  | 5,532      | (29)  | 992        | (31)  | 3,777       | (31)  | 44,808             | (37)  |
| Less patients with ILD in baseline period                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 262         | (3)   | 1,846      | (3)   | 354     | (1)   | 136        | (1)   | 60         | (2)   | 120         | (1)   | 2,778              | (2)   |
| Study Cohorts for ILD Outcome Analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5,437       | (60)  | 20,057     | (38)  | 6,551   | (27)  | 5,396      | (28)  | 932        | (29)  | 3,657       | (30)  | 42,030             | (35)  |
| 1. Among the HealthCore Integrated Research Database <sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. <sup>4</sup> The Epidemiology Study will be conducted using this patient population. Only the index study drug will be counted, therefore a patient is only counted once. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period. Percentages are reported as the number of patients identified divided by the number of patients with the first study drug assigned as the cohort. |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
| 2. Patients allowed to contribute to multiple index drug columns until excluding for multiple study drugs on index date. Blue-highlighted Total counts are unique patients and not the sum of counts across drug columns.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
| 3. Additional screening to reflect Epidemiology Study Protocol.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |
| 4. Per study-specific exemption recently granted by HealthCore leadership in Oct 2014 to allow the inclusion of administrative services opt-in patients for this study. Such patients were excluded in all previous accrual reports.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |             |       |            |       |         |       |            |       |            |       |             |       |                    |       |



**Table 2. Serious Liver Injury/Disease (SLD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup>**

| Events                                                               | Patients | Cumulative SLD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 30 Sep 2014) |              |              |              |            |              |            |              |            |              | Total SLD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(01 Dec 2013 - 30 Sep 2014) |              | Cum. Total SLD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 30 Sep 2014) |              |
|----------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|--------------|------------|--------------|------------|--------------|------------|--------------|-----------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
|                                                                      |          | Dronedaron                                                                                                                                  |              | Amiodaron    |              | Sotalol    |              | Flecainide |              | Dofetilide |              | Propafenone                                                                                                     |              | Total                                                                                                                                |              |
|                                                                      |          | 5,437                                                                                                                                       | 20,385       | 6,546        | 5,332        | 949        | 3,634        | 2,556      | 42,283       |            |              |                                                                                                                 |              |                                                                                                                                      |              |
|                                                                      |          | N                                                                                                                                           | (%)          | N            | (%)          | N          | (%)          | N          | (%)          | N          | (%)          | N                                                                                                               | (%)          | N                                                                                                                                    | (%)          |
| <b>Total with at least one occurrence of an SLD code<sup>5</sup></b> |          | <b>251</b>                                                                                                                                  | <b>(4.6)</b> | <b>1,276</b> | <b>(6.3)</b> | <b>324</b> | <b>(4.9)</b> | <b>172</b> | <b>(3.2)</b> | <b>51</b>  | <b>(5.4)</b> | <b>169</b>                                                                                                      | <b>(4.7)</b> | <b>84</b>                                                                                                                            | <b>(3.3)</b> |
| <b>Serious Liver Injury/Disease<sup>6</sup></b>                      |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                      |              |
| <b>ICD-9-CM Diagnoses</b>                                            |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                      |              |
| 277.4x Disorders of bilirubin excretion                              |          | 6                                                                                                                                           | (2.4)        | 31           | (2.4)        | 9          | (2.8)        | 4          | (2.3)        | 1          | (2.0)        | 3                                                                                                               | (1.8)        | 2                                                                                                                                    | (2.4)        |
| 570.xx Acute and subacute necrosis of liver                          |          | 17                                                                                                                                          | (6.8)        | 106          | (8.3)        | 21         | (6.5)        | 6          | (3.5)        | 2          | (3.9)        | 3                                                                                                               | (1.8)        | 8                                                                                                                                    | (9.5)        |
| 571.5x Cirrhosis of liver without mention of alcohol                 |          | 14                                                                                                                                          | (5.6)        | 76           | (6.0)        | 20         | (6.2)        | 5          | (2.9)        | 4          | (7.8)        | 8                                                                                                               | (4.7)        | 3                                                                                                                                    | (3.6)        |
| 572.2x Hepatic coma                                                  |          | 1                                                                                                                                           | (0.4)        | 16           | (1.3)        | 3          | (0.9)        | -          | (0.0)        | 1          | (2.0)        | 2                                                                                                               | (1.2)        | -                                                                                                                                    | (0.0)        |
| 572.4x Hepatorenal syndrome                                          |          | -                                                                                                                                           | (0.0)        | 4            | (0.3)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 572.8x Other sequelae of chronic liver disease                       |          | -                                                                                                                                           | (0.0)        | 15           | (1.2)        | 8          | (2.5)        | 3          | (1.7)        | -          | (0.0)        | 4                                                                                                               | (2.4)        | -                                                                                                                                    | (0.0)        |
| 573.0x Chronic passive congestion of liver                           |          | 2                                                                                                                                           | (0.8)        | 17           | (1.3)        | 2          | (0.6)        | -          | (0.0)        | -          | (0.0)        | 2                                                                                                               | (1.2)        | 1                                                                                                                                    | (1.2)        |
| 573.3x Hepatitis, unspecified                                        |          | 18                                                                                                                                          | (7.2)        | 117          | (9.2)        | 17         | (5.2)        | 11         | (6.4)        | 1          | (2.0)        | 9                                                                                                               | (5.3)        | 8                                                                                                                                    | (9.5)        |
| 573.8x Other specified disorders of liver                            |          | 81                                                                                                                                          | (32.3)       | 352          | (27.6)       | 101        | (31.2)       | 73         | (42.4)       | 21         | (41.2)       | 69                                                                                                              | (40.8)       | 27                                                                                                                                   | (32.1)       |
| 573.9x Unspecified disorder of liver                                 |          | 31                                                                                                                                          | (12.4)       | 134          | (10.5)       | 48         | (14.8)       | 18         | (10.5)       | 5          | (9.8)        | 20                                                                                                              | (11.8)       | 9                                                                                                                                    | (10.7)       |
| 782.4x Jaundice, unspecified                                         |          | 17                                                                                                                                          | (6.8)        | 103          | (8.1)        | 21         | (6.5)        | 14         | (8.1)        | 5          | (9.8)        | 14                                                                                                              | (8.3)        | 9                                                                                                                                    | (10.7)       |
| 794.8x Nonspecific abnormal results of liver function test           |          | 63                                                                                                                                          | (25.1)       | 330          | (25.9)       | 87         | (26.9)       | 41         | (23.8)       | 13         | (25.5)       | 41                                                                                                              | (24.3)       | 18                                                                                                                                   | (21.4)       |
| V42.7x Liver transplant status                                       |          | 1                                                                                                                                           | (0.4)        | 1            | (0.1)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| <b>ICD-9-CM Procedures</b>                                           |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                      |              |
| 50.11 Closed (percutaneous) [needle] biopsy of liver                 |          | 2                                                                                                                                           | (0.8)        | 16           | (1.3)        | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | 2                                                                                                               | (1.2)        | 2                                                                                                                                    | (2.4)        |
| 50.12 Open biopsy of liver                                           |          | -                                                                                                                                           | (0.0)        | 1            | (0.1)        | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.13 Transjugular liver biopsy                                      |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.14 Laparoscopic liver biopsy                                      |          | -                                                                                                                                           | (0.0)        | 3            | (0.2)        | 3          | (0.9)        | -          | (0.0)        | -          | (0.0)        | 1                                                                                                               | (0.6)        | -                                                                                                                                    | (0.0)        |
| 50.5x Liver transplant                                               |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.51 Auxiliary liver transplant                                     |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.59 Other transplant of liver                                      |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 50.91 Percutaneous aspiration of liver                               |          | -                                                                                                                                           | (0.0)        | 2            | (0.2)        | 2          | (0.6)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | 1                                                                                                                                    | (1.2)        |
| <b>CPT Procedures</b>                                                |          |                                                                                                                                             |              |              |              |            |              |            |              |            |              |                                                                                                                 |              |                                                                                                                                      |              |
| 47000 Biopsy of liver, needle; percutaneous                          |          | 1                                                                                                                                           | (0.4)        | 7            | (0.5)        | 2          | (0.6)        | 4          | (2.3)        | -          | (0.0)        | 5                                                                                                               | (3.0)        | 1                                                                                                                                    | (1.2)        |
| 47001 Biopsy of liver, needle; done at time of other major procedure |          | 1                                                                                                                                           | (0.4)        | 6            | (0.5)        | 1          | (0.3)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 47100 Biopsy of liver, wedge                                         |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | 2                                                                                                               | (1.2)        | -                                                                                                                                    | (0.0)        |
| 47135 Liver allotransplantation; orthotopic, partial or whole        |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 47136 Liver allotransplantation; heterotopic, partial or whole       |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 78205 Liver imaging (SPECT)                                          |          | -                                                                                                                                           | (0.0)        | 2            | (0.2)        | -          | (0.0)        | 1          | (0.6)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |
| 78206 Liver imaging (SPECT); with vascular flow                      |          | -                                                                                                                                           | (0.0)        | -            | (0.0)        | -          | (0.0)        | -          | (0.0)        | -          | (0.0)        | -                                                                                                               | (0.0)        | -                                                                                                                                    | (0.0)        |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population. For serious liver injury/disease (SLD) counts, patients with SLD in the baseline period were excluded.
2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all SLD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.
3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.
4. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period.
5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.
6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

**Table 3. Interstitial Lung Disease (ILD) Counts, By Cohort and Period, HealthCore Integrated Research Database<sup>SM</sup> (HIRD)<sup>1,2,3</sup>**

| Patients                                                            |  | Cumulative ILD Occurrences By Cohort<br>Among Patients Identified Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 30 Sep 2014) |        |                   |            |                |            |                   |            |                   |            | Total ILD Occurrences<br>Among Patients Identified<br>During Current Period Only<br>(01 Dec 2013 - 30 Sep 2014) |            | Cum. Total ILD Occurrences<br>Among Patients Identified<br>Through End of Current Period <sup>4</sup><br>(20 Jul 2009 - 30 Sep 2014) |            |          |            |
|---------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|-----------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------|------------|----------|------------|
|                                                                     |  | <u>Dronedarone</u>                                                                                                                          |        | <u>Amiodarone</u> |            | <u>Sotalol</u> |            | <u>Flecainide</u> |            | <u>Dofetilide</u> |            | <u>Propafenone</u>                                                                                              |            | <u>Total</u>                                                                                                                         |            |          |            |
|                                                                     |  | 5,437                                                                                                                                       |        | 20,057            |            | 6,551          |            | 5,396             |            | 932               |            | 3,657                                                                                                           |            | 2,585                                                                                                                                |            |          |            |
|                                                                     |  | Events                                                                                                                                      |        | <i>N</i>          | <i>(%)</i> | <i>N</i>       | <i>(%)</i> | <i>N</i>          | <i>(%)</i> | <i>N</i>          | <i>(%)</i> | <i>N</i>                                                                                                        | <i>(%)</i> | <i>N</i>                                                                                                                             | <i>(%)</i> | <i>N</i> | <i>(%)</i> |
| Total with at least one occurrence of an ILD code <sup>5</sup>      |  | 211                                                                                                                                         | (3.9)  | 1,229             | (6.1)      | 250            | (3.8)      | 98                | (1.8)      | 39                | (4.2)      | 101                                                                                                             | (2.8)      | 71                                                                                                                                   | (2.7)      | 1,928    | (4.6)      |
| Interstitial Lung Disease <sup>6</sup><br>ICD-9-CM Diagnoses        |  |                                                                                                                                             |        |                   |            |                |            |                   |            |                   |            |                                                                                                                 |            |                                                                                                                                      |            |          |            |
| 495.9x Unspecified allergic alveolitis and pneumonitis              |  | 2                                                                                                                                           | (0.9)  | 5                 | (0.4)      | 2              | (0.8)      | 1                 | (1.0)      | -                 | (0.0)      | 1                                                                                                               | (1.0)      | 2                                                                                                                                    | (2.8)      | 11       | (0.6)      |
| 515.xx Postinflammatory pulmonary fibrosis                          |  | 117                                                                                                                                         | (55.5) | 599               | (48.7)     | 149            | (59.6)     | 48                | (49.0)     | 20                | (51.3)     | 60                                                                                                              | (59.4)     | 36                                                                                                                                   | (50.7)     | 993      | (51.5)     |
| 516.3x Idiopathic fibrosing alveolitis                              |  | 10                                                                                                                                          | (4.7)  | 55                | (4.5)      | 12             | (4.8)      | 8                 | (8.2)      | 2                 | (5.1)      | 1                                                                                                               | (1.0)      | 4                                                                                                                                    | (5.6)      | 88       | (4.6)      |
| 516.30 Idiopathic interstitial pneumonia, not otherwise specified   |  | 3                                                                                                                                           | (1.4)  | 7                 | (0.6)      | 3              | (1.2)      | 2                 | (2.0)      | -                 | (0.0)      | 1                                                                                                               | (1.0)      | 1                                                                                                                                    | (1.4)      | 16       | (0.8)      |
| 516.31 Idiopathic pulmonary fibrosis                                |  | 2                                                                                                                                           | (0.9)  | 19                | (1.5)      | 4              | (1.6)      | 1                 | (1.0)      | 2                 | (5.1)      | -                                                                                                               | (0.0)      | 2                                                                                                                                    | (2.8)      | 28       | (1.5)      |
| 516.32 Idiopathic non-specific interstitial pneumonitis             |  | -                                                                                                                                           | (0.0)  | -                 | (0.0)      | -              | (0.0)      | 1                 | (1.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | -                                                                                                                                    | (0.0)      | 1        | (0.1)      |
| 516.33 Acute interstitial pneumonitis                               |  | -                                                                                                                                           | (0.0)  | 3                 | (0.2)      | -              | (0.0)      | -                 | (0.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | -                                                                                                                                    | (0.0)      | 3        | (0.2)      |
| 516.34 Respiratory bronchiolitis interstitial lung disease          |  | 1                                                                                                                                           | (0.5)  | 2                 | (0.2)      | -              | (0.0)      | 1                 | (1.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | -                                                                                                                                    | (0.0)      | 4        | (0.2)      |
| 516.35 Idiopathic lymphoid interstitial pneumonia                   |  | -                                                                                                                                           | (0.0)  | -                 | (0.0)      | -              | (0.0)      | -                 | (0.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | -                                                                                                                                    | (0.0)      | -        | (0.0)      |
| 516.36 Cryptogenic organizing pneumonia                             |  | -                                                                                                                                           | (0.0)  | 2                 | (0.2)      | -              | (0.0)      | -                 | (0.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | 1                                                                                                                                    | (1.4)      | 2        | (0.1)      |
| 516.37 Desquamative interstitial pneumonia                          |  | -                                                                                                                                           | (0.0)  | -                 | (0.0)      | -              | (0.0)      | -                 | (0.0)      | -                 | (0.0)      | -                                                                                                               | (0.0)      | -                                                                                                                                    | (0.0)      | -        | (0.0)      |
| 516.8x Other specified alveolar and parietoalveolar pneumonopathies |  | 5                                                                                                                                           | (2.4)  | 42                | (3.4)      | 4              | (1.6)      | 4                 | (4.1)      | -                 | (0.0)      | 4                                                                                                               | (4.0)      | 2                                                                                                                                    | (2.8)      | 59       | (3.1)      |
| 516.9x Unspecified alveolar and parietoalveolar pneumonopathy       |  | 9                                                                                                                                           | (4.3)  | 32                | (2.6)      | 7              | (2.8)      | 4                 | (4.1)      | 1                 | (2.6)      | 2                                                                                                               | (2.0)      | -                                                                                                                                    | (0.0)      | 55       | (2.9)      |
| 518.82 Adult respiratory distress syndrome                          |  | 70                                                                                                                                          | (33.2) | 517               | (42.1)     | 84             | (33.6)     | 35                | (35.7)     | 16                | (41.0)     | 34                                                                                                              | (33.7)     | 28                                                                                                                                   | (39.4)     | 756      | (39.2)     |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population. For interstitial lung disease (ILD) counts, patients with ILD in the baseline period were excluded.

2. Since we are following patients from the index cohort until the end of the monitoring period, death, or disenrollment from their health plan, all ILD cases will be captured regardless of whether the patient stayed on the index drug or switched to another drug.

3. Counts by code are not mutually exclusive; a patient can be counted in multiple rows if the patient had multiple codes on the event date.

4. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period.

5. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of patients identified in the cohort and specified period.

6. Percentages are reported as the number of events identified in the cohort and specified period divided by the total number of events identified in the cohort and specified period.

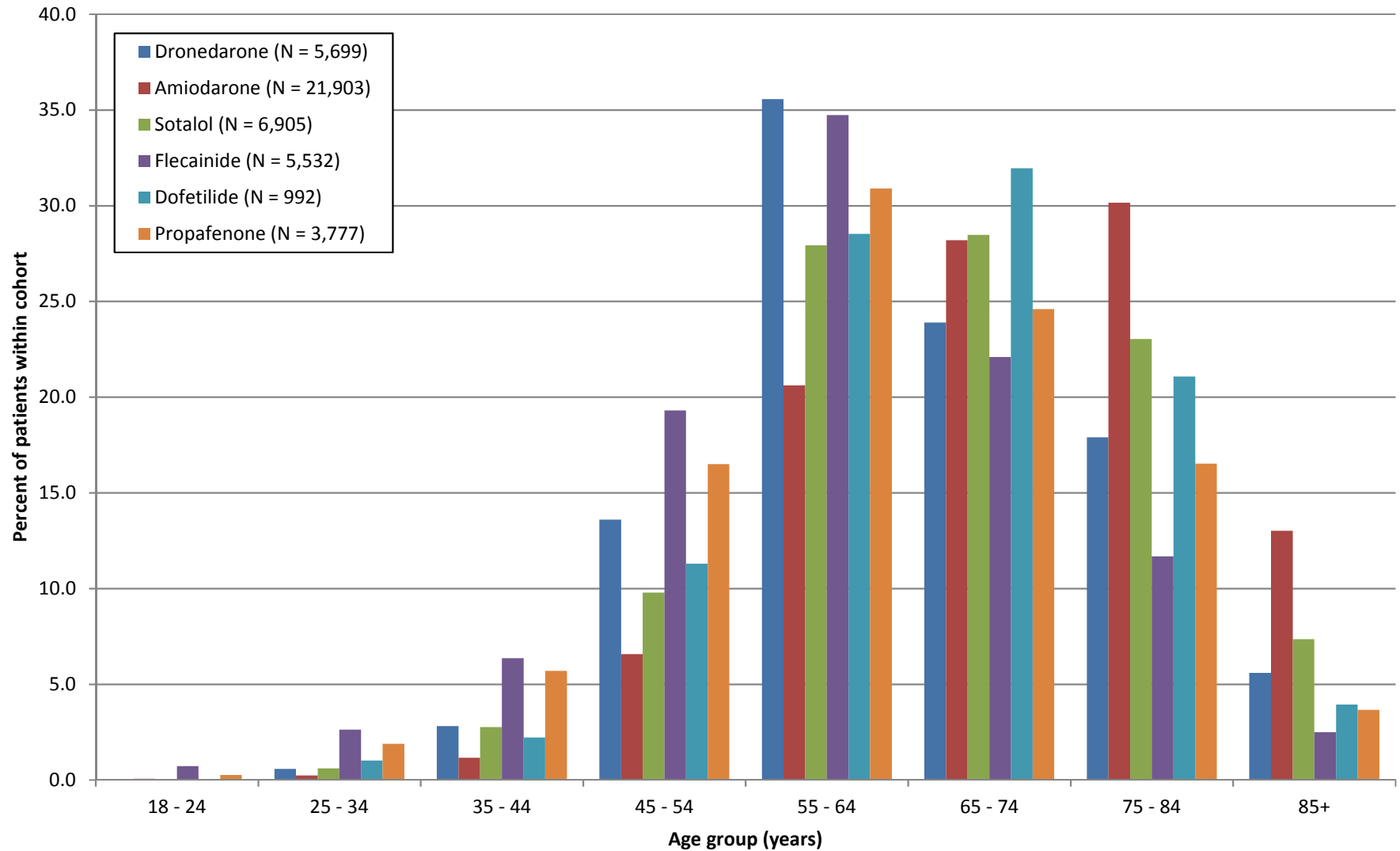
|                                                                                           | <b>Dronedarone</b> |               | <b>Amiodarone</b> |               | <b>Sotalol</b> |               | <b>Flecainide</b> |               | <b>Dofetilide</b> |              | <b>Propafenone</b> |              | <b>Total</b>  |        |
|-------------------------------------------------------------------------------------------|--------------------|---------------|-------------------|---------------|----------------|---------------|-------------------|---------------|-------------------|--------------|--------------------|--------------|---------------|--------|
| <b>Patients</b>                                                                           | <i>N</i>           | (%)           | <i>N</i>          | (%)           | <i>N</i>       | (%)           | <i>N</i>          | (%)           | <i>N</i>          | (%)          | <i>N</i>           | (%)          | <i>N</i>      | (%)    |
| <b>Total patients identified through end of current period, 20 Jul 2009 - 31 Mar 2014</b> | <b>5,699</b>       | <b>(12.7)</b> | <b>21,903</b>     | <b>(48.9)</b> | <b>6,905</b>   | <b>(15.4)</b> | <b>5,532</b>      | <b>(12.3)</b> | <b>992</b>        | <b>(2.2)</b> | <b>3,777</b>       | <b>(8.4)</b> | <b>44,808</b> |        |
| <b>Age group (years)</b>                                                                  |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |        |
| 18 - 24                                                                                   | 3                  | (0.1)         | 12                | (0.1)         | 3              | (0.0)         | 40                | (0.7)         | -                 | (0.0)        | 10                 | (0.3)        | 68            | (0.2)  |
| 25 - 34                                                                                   | 33                 | (0.6)         | 52                | (0.2)         | 42             | (0.6)         | 145               | (2.6)         | 10                | (1.0)        | 71                 | (1.9)        | 353           | (0.8)  |
| 35 - 44                                                                                   | 160                | (2.8)         | 254               | (1.2)         | 191            | (2.8)         | 352               | (6.4)         | 22                | (2.2)        | 215                | (5.7)        | 1,194         | (2.7)  |
| 45 - 54                                                                                   | 775                | (13.6)        | 1,439             | (6.6)         | 676            | (9.8)         | 1,068             | (19.3)        | 112               | (11.3)       | 623                | (16.5)       | 4,693         | (10.5) |
| 55 - 64                                                                                   | 2,027              | (35.6)        | 4,515             | (20.6)        | 1,929          | (27.9)        | 1,921             | (34.7)        | 283               | (28.5)       | 1,167              | (30.9)       | 11,842        | (26.4) |
| 65 - 74                                                                                   | 1,362              | (23.9)        | 6,175             | (28.2)        | 1,966          | (28.5)        | 1,222             | (22.1)        | 317               | (32.0)       | 929                | (24.6)       | 11,971        | (26.7) |
| 75 - 84                                                                                   | 1,020              | (17.9)        | 6,604             | (30.2)        | 1,590          | (23.0)        | 646               | (11.7)        | 209               | (21.1)       | 624                | (16.5)       | 10,693        | (23.9) |
| 85+                                                                                       | 319                | (5.6)         | 2,852             | (13.0)        | 508            | (7.4)         | 138               | (2.5)         | 39                | (3.9)        | 138                | (3.7)        | 3,994         | (8.9)  |
| <b>Age group, female (years)</b>                                                          |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |        |
| 18 - 24, female                                                                           | 2                  | (0.1)         | 3                 | (0.0)         | 1              | (0.0)         | 4                 | (0.2)         | .                 | (0.0)        | 3                  | (0.2)        | 13            | (0.1)  |
| 25 - 34, female                                                                           | 5                  | (0.2)         | 8                 | (0.1)         | 8              | (0.3)         | 30                | (1.3)         | 1                 | (0.3)        | 11                 | (0.7)        | 63            | (0.4)  |
| 35 - 44, female                                                                           | 33                 | (1.6)         | 39                | (0.5)         | 28             | (1.0)         | 95                | (4.0)         | 4                 | (1.3)        | 38                 | (2.5)        | 237           | (1.4)  |
| 45 - 54, female                                                                           | 174                | (8.4)         | 291               | (3.5)         | 190            | (6.6)         | 340               | (14.4)        | 22                | (6.9)        | 138                | (9.1)        | 1,155         | (6.6)  |
| 55 - 64, female                                                                           | 612                | (29.6)        | 1,063             | (12.8)        | 593            | (20.6)        | 741               | (31.4)        | 73                | (22.9)       | 407                | (26.8)       | 3,489         | (20.0) |
| 65 - 74, female                                                                           | 518                | (25.1)        | 2,053             | (24.8)        | 838            | (29.1)        | 611               | (25.9)        | 101               | (31.7)       | 450                | (29.6)       | 4,571         | (26.2) |
| 75 - 84, female                                                                           | 517                | (25.0)        | 3,059             | (36.9)        | 875            | (30.4)        | 429               | (18.2)        | 91                | (28.5)       | 377                | (24.8)       | 5,348         | (30.7) |
| 85+, female                                                                               | 205                | (9.9)         | 1,764             | (21.3)        | 342            | (11.9)        | 108               | (4.6)         | 27                | (8.5)        | 94                 | (6.2)        | 2,540         | (14.6) |
| <b>Age group, male (years)</b>                                                            |                    |               |                   |               |                |               |                   |               |                   |              |                    |              |               |        |
| 18 - 24, male                                                                             | 1                  | (0.0)         | 9                 | (0.1)         | 2              | (0.0)         | 36                | (1.1)         | .                 | (0.0)        | 7                  | (0.3)        | 55            | (0.2)  |
| 25 - 34, male                                                                             | 28                 | (0.8)         | 44                | (0.3)         | 34             | (0.8)         | 115               | (3.6)         | 9                 | (1.3)        | 60                 | (2.7)        | 290           | (1.1)  |
| 35 - 44, male                                                                             | 127                | (3.5)         | 215               | (1.6)         | 163            | (4.0)         | 257               | (8.1)         | 18                | (2.7)        | 177                | (7.8)        | 957           | (3.5)  |
| 45 - 54, male                                                                             | 601                | (16.5)        | 1,148             | (8.4)         | 486            | (12.1)        | 728               | (22.9)        | 90                | (13.4)       | 485                | (21.5)       | 3,538         | (12.9) |
| 55 - 64, male                                                                             | 1,415              | (38.9)        | 3,452             | (25.3)        | 1,336          | (33.2)        | 1,180             | (37.2)        | 210               | (31.2)       | 760                | (33.6)       | 8,353         | (30.5) |
| 65 - 74, male                                                                             | 844                | (23.2)        | 4,122             | (30.3)        | 1,128          | (28.0)        | 611               | (19.3)        | 216               | (32.1)       | 479                | (21.2)       | 7,400         | (27.0) |
| 75 - 84, male                                                                             | 503                | (13.8)        | 3,545             | (26.0)        | 715            | (17.7)        | 217               | (6.8)         | 118               | (17.5)       | 247                | (10.9)       | 5,345         | (19.5) |
| 85+, male                                                                                 | 114                | (3.1)         | 1,088             | (8.0)         | 166            | (4.1)         | 30                | (0.9)         | 12                | (1.8)        | 44                 | (1.9)        | 1,454         | (5.3)  |

1. Among the HealthCore Integrated Research Database<sup>SM</sup> (HIRD) population including both fully insured and administrative services only (ASO) members, for whom claims profiles can now be shared externally outside of HealthCore, Inc. Such patients were excluded in all previous accrual reports. The Epidemiology Study will be conducted using this patient population.

2. Only the index study drug will be counted, therefore a patient is only counted once.

3. Epidemiology Study Protocol patient identification and inclusion/exclusion criteria were assessed for all patients identified through the end of the current period. Patients with serious liver injury/disease (SLD) or interstitial lung disease (ILD) in the baseline period were not excluded.

**Age Distribution of Index Users, By Cohort,  
Through End of Current Period (20 Jul 2009 - 31 Mar 2014),  
HealthCore Integrated Research Database<sup>SM</sup> (HIRD)**



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## **APPENDIX 6. SAMPLE PATIENT PROFILES**

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## PATIENT PROFILE LAYOUT

**Header information - this information lists the Patient ID, gender, age at index date, Index Date, and date of suspected outcome event.**

| Patient ID #      | Age:                               | Gender:        | Index Date:              | Event Date:                                                        | Date of Death: |
|-------------------|------------------------------------|----------------|--------------------------|--------------------------------------------------------------------|----------------|
| De-identified ID# | Patient's age as of the Index Date | Male or Female | Date of Index Study Drug | First occurrence after the index date of a suspected outcome event | Date of Death  |

**Patient's Medical History - medical/pharmacy encounter data is laid out in chronological order by the services rendered, oldest records appearing at the beginning and recent records at the bottom.**

| Line # | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code | POS | Provider Specialty | Seq # | Code Description | Medication Name | Days Supply | QTY | Drug Formulation | Source | Record # |
|--------|-----------------|-----------------------------|----------------|-----------|------|-----|--------------------|-------|------------------|-----------------|-------------|-----|------------------|--------|----------|
|--------|-----------------|-----------------------------|----------------|-----------|------|-----|--------------------|-------|------------------|-----------------|-------------|-----|------------------|--------|----------|

### Column definitions:

|                              |                                                                                                                                                                                                                                                                    |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Line #                       | Sequential line number beginning with "1"                                                                                                                                                                                                                          |
| Time from Index              | Displays the number of days prior to the index date (e.g., -180, 180 days prior to the index date); and the number of days after the index date (e.g., 240)                                                                                                        |
| Date of Service / Admit Date | Contains the date of service for medical and pharmacy transactions. For inpatient stays, this date is the admission date.                                                                                                                                          |
| Discharge Date               | For code type=DX, PX, and CPT this date is the inpatient discharge date for inpatient stays.                                                                                                                                                                       |
| Code Type                    | Identifies the type of service transaction: <b>DX</b> = ICD-9-CM diagnosis code; <b>PX</b> = ICD-9-CM procedure code, CPT code, or HCPCS code; <b>RX</b> = Medication                                                                                              |
| Code                         | Actual code value reported for that transaction. For example, ICD-9-CM diagnosis/procedure codes, CPT codes, National Drug Codes (NDC)                                                                                                                             |
| POS                          | Place of Treatment (Services): Inpt (Hospital inpatient) indicates services that were performed at an inpatient hospital setting.                                                                                                                                  |
| Provider Specialty           | See Provider Specialty Codes Tabs for definitions                                                                                                                                                                                                                  |
| Seq #                        | The order in which the <b>diagnosis codes</b> appear on the claim/record form. 1=Primary, 2= secondary, etc...                                                                                                                                                     |
| Code Description             | Corresponding description of the code.                                                                                                                                                                                                                             |
| Medication Name              | Name of the medication dispensed                                                                                                                                                                                                                                   |
| Days Supply                  | For RX records, this value is the Days Supply.                                                                                                                                                                                                                     |
| QTY                          | For RX records, this value is the quantity dispensed.                                                                                                                                                                                                              |
| Drug Formulation             | For RX records, this is the drug formulation.                                                                                                                                                                                                                      |
| Source                       | This is the source of the transaction. <b>CAPER</b> =Direct Care-ProfessionalServices; <b>SIDR</b> =Direct Care-Inpt Records; <b>TEDN</b> =Purchased Care-Professional Services; <b>TEDI</b> =Purchased Care-Inpt Records; <b>PDTS</b> =Pharmacy Data Transactions |
| Record #                     | This number identifies the services/encounters associated with a transaction. There may be more than one transaction on a single day.                                                                                                                              |

### Color Coding

|                  |                                                                |
|------------------|----------------------------------------------------------------|
| Yellow highlight | Index study drugs are highlighted in yellow.                   |
| Orange highlight | Non-index study drugs are highlighted in orange.               |
| Olive highlight  | Skilled nursing facility stays are highlighted in olive green. |

Hospitalizations (admit to discharge) are highlighted in gray.

**Hospital Facility Records containing discharge diagnoses/procedures are in bold black text.**

**Hospitalized outcome events of interest are in bold red text.**

Non-hospitalized outcome events will be in plain red text.

Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 1           | -357            | 12/15/2008                  |                | Rx        | 00832121510 |     |                    |       |                                           | Jantoven               | 90          | 90  | Tablet                         | PDTS   | 1      |
| 2           | -355            | 12/17/2008                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 2      |
| 3           | -321            | 01/20/2009                  |                | Dx        | 34540       |     | Neuro              | 1     | Loc Epilepsy W Complex Seizure            |                        |             |     |                                | TEDN   | 3      |
| 4           | -321            | 01/20/2009                  |                | Px        | 99213       |     | Neuro              | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 3      |
| 5           | -315            | 01/26/2009                  |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 4      |
| 6           | -312            | 01/29/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 5      |
| 7           | -312            | 01/29/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 5      |
| 8           | -312            | 01/29/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 5      |
| 9           | -312            | 01/29/2009                  |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 5      |
| 10          | -298            | 02/12/2009                  |                | Dx        | 5853        |     | Grppract           | 1     | Chronic Kidney Disease Stage Iii          |                        |             |     |                                | TEDN   | 7      |
| 11          | -298            | 02/12/2009                  |                | Dx        | 2859        |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 7      |
| 12          | -298            | 02/12/2009                  |                | Dx        | 4011        |     | Grppract           | 3     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 7      |
| 13          | -298            | 02/12/2009                  |                | Px        | 99212       |     | Grppract           | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                | TEDN   | 7      |
| 14          | -298            | 02/12/2009                  |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide             | 30          | 60  | Tablet                         | PDTS   | 6      |
| 15          | -284            | 02/26/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 8      |
| 16          | -284            | 02/26/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 8      |
| 17          | -284            | 02/26/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 8      |
| 18          | -284            | 02/26/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 8      |
| 19          | -284            | 02/26/2009                  |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 9      |
| 20          | -284            | 02/26/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 10     |
| 21          | -278            | 03/04/2009                  |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                                | TEDN   | 11     |
| 22          | -278            | 03/04/2009                  |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                                | TEDN   | 11     |
| 23          | -278            | 03/04/2009                  |                | Px        | A4371       |     | Medic              | 1     | Skin Barrier Powder Per Oz                |                        |             |     |                                | TEDN   | 12     |
| 24          | -278            | 03/04/2009                  |                | Px        | A4394       |     | Medic              | 1     | Ostomy Pouch Liq Deodorant                |                        |             |     |                                | TEDN   | 13     |
| 25          | -278            | 03/04/2009                  |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                                | TEDN   | 14     |
| 26          | -278            | 03/04/2009                  |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                                | TEDN   | 15     |
| 27          | -278            | 03/04/2009                  |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                                | TEDN   | 16     |
| 28          | -278            | 03/04/2009                  |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                                | TEDN   | 17     |
| 29          | -276            | 03/06/2009                  |                | Rx        | 25010040515 |     |                    |       |                                           | Mephyton               | 1           | 2   | Tablet                         | PDTS   | 18     |
| 30          | -275            | 03/07/2009                  |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 30          | 60  | Tablet, Sustained Release 24hr | PDTS   | 19     |
| 31          | -273            | 03/09/2009                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 20     |
| 32          | -270            | 03/12/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 21     |
| 33          | -270            | 03/12/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 21     |
| 34          | -270            | 03/12/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 21     |
| 35          | -270            | 03/12/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 21     |
| 36          | -270            | 03/12/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 22     |
| 37          | -269            | 03/13/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                         | PDTS   | 23     |
| 38          | -265            | 03/17/2009                  |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 24     |
| 39          | -261            | 03/21/2009                  |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide             | 30          | 60  | Tablet                         | PDTS   | 25     |

Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description      | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|--------------------------------|--------|--------|
| 40          | -242            | 04/09/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 26     |
| 41          | -242            | 04/09/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 26     |
| 42          | -242            | 04/09/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 26     |
| 43          | -242            | 04/09/2009                  |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 26     |
| 44          | -238            | 04/13/2009                  |                | Rx        | 49884040501 |     |                    |       |                                           | Metoprolol Succinate        | 30          | 90  | Tablet, Sustained Release 24hr | PDTS   | 27     |
| 45          | -237            | 04/14/2009                  |                | Rx        | 62175011843 |     |                    |       |                                           | Omeprazole                  | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 28     |
| 46          | -231            | 04/20/2009                  |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                                | TEDN   | 29     |
| 47          | -231            | 04/20/2009                  |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                             |             |     |                                | TEDN   | 29     |
| 48          | -231            | 04/20/2009                  |                | Dx        | 2720        |     | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                             |             |     |                                | TEDN   | 29     |
| 49          | -231            | 04/20/2009                  |                | Dx        | 5939        |     | Cardvasc           | 4     | Uns Disorder Kidney/Ureter                |                             |             |     |                                | TEDN   | 29     |
| 50          | -231            | 04/20/2009                  |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 29     |
| 51          | -230            | 04/21/2009                  |                | Rx        | 68462014645 |     |                    |       |                                           | Nitroglycerin               | 15          | 25  | Tablet, Sublingual             | PDTS   | 30     |
| 52          | -228            | 04/23/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 31     |
| 53          | -228            | 04/23/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 31     |
| 54          | -228            | 04/23/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 31     |
| 55          | -228            | 04/23/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                             |             |     |                                | TEDN   | 31     |
| 56          | -228            | 04/23/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                             |             |     |                                | TEDN   | 32     |
| 57          | -227            | 04/24/2009                  |                | Dx        | 42731       |     | Grppract           | 1     | Atrial Fibrillation                       |                             |             |     |                                | TEDN   | 33     |
| 58          | -227            | 04/24/2009                  |                | Dx        | 41400       |     | Grppract           | 2     | Coronary Athrscler Uns Vessel             |                             |             |     |                                | TEDN   | 33     |
| 59          | -227            | 04/24/2009                  |                | Dx        | 2449        |     | Grppract           | 3     | Uns Hypothyroidism                        |                             |             |     |                                | TEDN   | 33     |
| 60          | -227            | 04/24/2009                  |                | Dx        | 53081       |     | Grppract           | 4     | Esophageal Reflux                         |                             |             |     |                                | TEDN   | 33     |
| 61          | -227            | 04/24/2009                  |                | Px        | 99499       |     | Grppract           | 1     | Unlisted Evaluation And Management Servic |                             |             |     |                                | TEDN   | 33     |
| 62          | -220            | 05/01/2009                  |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                     | 30          | 36  | Capsule (Hard, Soft, Etc.)     | PDTS   | 34     |
| 63          | -218            | 05/03/2009                  |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL                   | 90          | 180 | Tablet, Sustained Release 24hr | PDTS   | 35     |
| 64          | -214            | 05/07/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                         | PDTS   | 36     |
| 65          | -203            | 05/18/2009                  |                | Rx        | 00093089005 |     |                    |       |                                           | Propoxyphene Napsylate-Apap | 15          | 60  | Tablet                         | PDTS   | 37     |
| 66          | -200            | 05/21/2009                  |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                     | 56          | 72  | Capsule (Hard, Soft, Etc.)     | PDTS   | 38     |
| 67          | -189            | 06/01/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                         | PDTS   | 39     |
| 68          | -189            | 06/01/2009                  |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide                  | 30          | 60  | Tablet                         | PDTS   | 40     |
| 69          | -186            | 06/04/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 41     |
| 70          | -186            | 06/04/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 41     |
| 71          | -186            | 06/04/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 41     |
| 72          | -186            | 06/04/2009                  |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 41     |
| 73          | -186            | 06/04/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                             |             |     |                                | TEDN   | 42     |
| 74          | -184            | 06/06/2009                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                         | PDTS   | 43     |
| 75          | -184            | 06/06/2009                  |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin                 | 90          | 90  | Tablet                         | PDTS   | 44     |
| 76          | -174            | 06/16/2009                  |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin                  | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 45     |
| 77          | -172            | 06/18/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 46     |
| 78          | -172            | 06/18/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 46     |



Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 79          | -172            | 06/18/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 46     |
| 80          | -172            | 06/18/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 46     |
| 81          | -172            | 06/18/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 47     |
| 82          | -154            | 07/06/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                         | PDTS   | 48     |
| 83          | -153            | 07/07/2009                  |                | Dx        | 34540       |     | Neuro              | 1     | Loc Epilepsy W Complex Seizure            |                        |             |     |                                | TEDN   | 49     |
| 84          | -153            | 07/07/2009                  |                | Px        | 99214       |     | Neuro              | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 49     |
| 85          | -147            | 07/13/2009                  |                | Dx        | V431        |     | Ophth              | 1     | Lens Replaced By Oth Means                |                        |             |     |                                | TEDN   | 51     |
| 86          | -147            | 07/13/2009                  |                | Px        | 92014       |     | Ophth              | 1     | Ophth Medical Xm&eval Comprhnsv Estab Pt  |                        |             |     |                                | TEDN   | 51     |
| 87          | -147            | 07/13/2009                  |                | Px        | 92015       |     | Ophth              | 1     | Determination Refractive State            |                        |             |     |                                | TEDN   | 52     |
| 88          | -147            | 07/13/2009                  |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 50     |
| 89          | -146            | 07/14/2009                  |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                                | TEDN   | 53     |
| 90          | -146            | 07/14/2009                  |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                                | TEDN   | 53     |
| 91          | -146            | 07/14/2009                  |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                                | TEDN   | 54     |
| 92          | -146            | 07/14/2009                  |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                                | TEDN   | 55     |
| 93          | -146            | 07/14/2009                  |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                                | TEDN   | 56     |
| 94          | -146            | 07/14/2009                  |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                                | TEDN   | 57     |
| 95          | -144            | 07/16/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 58     |
| 96          | -144            | 07/16/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 58     |
| 97          | -144            | 07/16/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 58     |
| 98          | -144            | 07/16/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 58     |
| 99          | -144            | 07/16/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 59     |
| 100         | -140            | 07/20/2009                  |                | Rx        | 60429015701 |     |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 60     |
| 101         | -130            | 07/30/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 61     |
| 102         | -130            | 07/30/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 61     |
| 103         | -130            | 07/30/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 61     |
| 104         | -130            | 07/30/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 61     |
| 105         | -130            | 07/30/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 62     |
| 106         | -130            | 07/30/2009                  |                | Dx        | 5853        |     | Grpprac            | 1     | Chronic Kidney Disease Stage Iii          |                        |             |     |                                | TEDN   | 63     |
| 107         | -130            | 07/30/2009                  |                | Dx        | 2859        |     | Grpprac            | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 63     |
| 108         | -130            | 07/30/2009                  |                | Dx        | 58881       |     | Grpprac            | 3     | Sec Hyperparathyroidism Renal             |                        |             |     |                                | TEDN   | 63     |
| 109         | -130            | 07/30/2009                  |                | Dx        | 4011        |     | Grpprac            | 4     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 63     |
| 110         | -130            | 07/30/2009                  |                | Px        | 99213       |     | Grpprac            | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 63     |
| 111         | -126            | 08/03/2009                  |                | Rx        | 64125011610 |     |                    |       |                                           | Furosemide             | 90          | 90  | Tablet                         | PDTS   | 64     |
| 112         | -114            | 08/15/2009                  |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 65     |
| 113         | -102            | 08/27/2009                  |                | Rx        | 68382005401 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                         | PDTS   | 66     |
| 114         | -98             | 08/31/2009                  |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 67     |
| 115         | -97             | 09/01/2009                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 68     |
| 116         | -91             | 09/07/2009                  |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 69     |
| 117         | -88             | 09/10/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 70     |

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| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 118         | -88             | 09/10/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 70     |
| 119         | -88             | 09/10/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 70     |
| 120         | -88             | 09/10/2009                 |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 70     |
| 121         | -74             | 09/24/2009                 |                | Dx        | 2859        |     | Patho              | 1     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 71     |
| 122         | -74             | 09/24/2009                 |                | Px        | 83912       |     | Patho              | 1     | Molecular Diagnostics Interpretation & Re |                        |             |     |                                | TEDN   | 71     |
| 123         | -71             | 09/27/2009                 |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 72     |
| 124         | -69             | 09/29/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 73     |
| 125         | -60             | 10/08/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 74     |
| 126         | -60             | 10/08/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 74     |
| 127         | -60             | 10/08/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 74     |
| 128         | -60             | 10/08/2009                 |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 74     |
| 129         | -60             | 10/08/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 75     |
| 130         | -48             | 10/20/2009                 |                | Dx        | 4293        |     | Grppract           | 1     | Cardiomegaly                              |                        |             |     |                                | TEDN   | 76     |
| 131         | -48             | 10/20/2009                 |                | Px        | 71020       |     | Grppract           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                | TEDN   | 76     |
| 132         | -48             | 10/20/2009                 |                | Px        | 93010       |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                                | TEDN   | 77     |
| 133         | -48             | 10/20/2009                 |                | Dx        | 78650       |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                                | TEDN   | 78     |
| 134         | -48             | 10/20/2009                 |                | Dx        | 78605       |     | Facility           | 2     | Shortness Breath                          |                        |             |     |                                | TEDN   | 78     |
| 135         | -48             | 10/20/2009                 |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 78     |
| 136         | -48             | 10/20/2009                 |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                                | TEDN   | 78     |
| 137         | -48             | 10/20/2009                 |                | Dx        | 34590       |     | Facility           | 5     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                                | TEDN   | 78     |
| 138         | -48             | 10/20/2009                 |                | Dx        | 73300       |     | Facility           | 6     | Osteoporosis Unspec                       |                        |             |     |                                | TEDN   | 78     |
| 139         | -48             | 10/20/2009                 |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                                | TEDN   | 78     |
| 140         | -48             | 10/20/2009                 |                | Dx        | 53081       |     | Facility           | 8     | Esophageal Reflux                         |                        |             |     |                                | TEDN   | 78     |
| 141         | -48             | 10/20/2009                 |                | Px        | 36415       |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                                | TEDN   | 78     |
| 142         | -48             | 10/20/2009                 |                | Px        | 80053       |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                                | TEDN   | 79     |
| 143         | -48             | 10/20/2009                 |                | Px        | 82553       |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                                | TEDN   | 80     |
| 144         | -48             | 10/20/2009                 |                | Px        | 83735       |     | Facility           | 1     | Magnesium                                 |                        |             |     |                                | TEDN   | 81     |
| 145         | -48             | 10/20/2009                 |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                                | TEDN   | 82     |
| 146         | -48             | 10/20/2009                 |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                                | TEDN   | 83     |
| 147         | -48             | 10/20/2009                 |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                                | TEDN   | 84     |
| 148         | -48             | 10/20/2009                 |                | Px        | 85730       |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                                | TEDN   | 85     |
| 149         | -48             | 10/20/2009                 |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                                | TEDN   | 86     |
| 150         | -48             | 10/20/2009                 |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                                | TEDN   | 87     |
| 151         | -48             | 10/20/2009                 |                | Px        | 99284       |     | Facility           | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                                | TEDN   | 88     |
| 152         | -48             | 10/20/2009                 |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                                | TEDN   | 89     |
| 153         | -47             | 10/21/2009                 |                | Dx        | 78650       |     | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                                | TEDN   | 90     |
| 154         | -47             | 10/21/2009                 |                | Dx        | 42731       |     | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 90     |
| 155         | -47             | 10/21/2009                 |                | Dx        | 4019        |     | Fp                 | 3     | Unspecified Essential Hypertension        |                        |             |     |                                | TEDN   | 90     |
| 156         | -47             | 10/21/2009                 |                | Dx        | 78039       |     | Fp                 | 4     | Other Convulsions                         |                        |             |     |                                | TEDN   | 90     |

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| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation           | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 157         | -47             | 10/21/2009                 |                | Px        | 99234       |     | Fp                 | 1     | Observation/Inpatient Hospital Care Low S |                        |             |     |                            | TEDN   | 90     |
| 158         | -47             | 10/21/2009                 |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                            | TEDN   | 91     |
| 159         | -47             | 10/21/2009                 |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                            | TEDN   | 91     |
| 160         | -47             | 10/21/2009                 |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                            | TEDN   | 92     |
| 161         | -47             | 10/21/2009                 |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                            | TEDN   | 93     |
| 162         | -47             | 10/21/2009                 |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                            | TEDN   | 94     |
| 163         | -47             | 10/21/2009                 |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                            | TEDN   | 95     |
| 164         | -47             | 10/21/2009                 |                | Dx        | 78650       |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                            | TEDN   | 96     |
| 165         | -47             | 10/21/2009                 |                | Dx        | 78605       |     | Facility           | 2     | Shortness Breath                          |                        |             |     |                            | TEDN   | 96     |
| 166         | -47             | 10/21/2009                 |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 96     |
| 167         | -47             | 10/21/2009                 |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                            | TEDN   | 96     |
| 168         | -47             | 10/21/2009                 |                | Dx        | 34590       |     | Facility           | 5     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                            | TEDN   | 96     |
| 169         | -47             | 10/21/2009                 |                | Dx        | 73300       |     | Facility           | 6     | Osteoporosis Unspec                       |                        |             |     |                            | TEDN   | 96     |
| 170         | -47             | 10/21/2009                 |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                            | TEDN   | 96     |
| 171         | -47             | 10/21/2009                 |                | Dx        | 53081       |     | Facility           | 8     | Esophageal Reflux                         |                        |             |     |                            | TEDN   | 96     |
| 172         | -47             | 10/21/2009                 |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                            | TEDN   | 96     |
| 173         | -47             | 10/21/2009                 |                | Px        | 82553       |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                            | TEDN   | 97     |
| 174         | -47             | 10/21/2009                 |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                            | TEDN   | 98     |
| 175         | -47             | 10/21/2009                 |                | Px        | 94760       |     | Facility           | 1     | Noninvasive Ear/Pulse Oximetry Single Det |                        |             |     |                            | TEDN   | 99     |
| 176         | -47             | 10/21/2009                 |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                            | TEDN   | 100    |
| 177         | -47             | 10/21/2009                 |                | Px        | 99234       |     | Facility           | 1     | Observation/Inpatient Hospital Care Low S |                        |             |     |                            | TEDN   | 101    |
| 178         | -46             | 10/22/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                            | TEDN   | 102    |
| 179         | -46             | 10/22/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                            | TEDN   | 102    |
| 180         | -46             | 10/22/2009                 |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                            | TEDN   | 102    |
| 181         | -46             | 10/22/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                            | TEDN   | 103    |
| 182         | -39             | 10/29/2009                 |                | Dx        | 78650       |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                            | TEDN   | 104    |
| 183         | -39             | 10/29/2009                 |                | Dx        | 53081       |     | Grppract           | 2     | Esophageal Reflux                         |                        |             |     |                            | TEDN   | 104    |
| 184         | -39             | 10/29/2009                 |                | Px        | 99499       |     | Grppract           | 1     | Unlisted Evaluation And Management Servic |                        |             |     |                            | TEDN   | 104    |
| 185         | -37             | 10/31/2009                 |                | Rx        | 62175011843 |     |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)      | PDTS   | 105    |
| 186         | -36             | 11/01/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.) | PDTS   | 106    |
| 187         | -33             | 11/04/2009                 |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 107    |
| 188         | -33             | 11/04/2009                 |                | Dx        | V171        |     | Cardvasc           | 2     | Family History Stroke                     |                        |             |     |                            | TEDN   | 107    |
| 189         | -33             | 11/04/2009                 |                | Dx        | V5869       |     | Cardvasc           | 3     | Encounter Long Term Use Oth Drugs         |                        |             |     |                            | TEDN   | 107    |
| 190         | -33             | 11/04/2009                 |                | Px        | 99242       |     | Cardvasc           | 1     | Office Consultation New/Estab Patient 30  |                        |             |     |                            | TEDN   | 107    |
| 191         | -18             | 11/19/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                            | TEDN   | 108    |
| 192         | -18             | 11/19/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                            | TEDN   | 108    |
| 193         | -18             | 11/19/2009                 |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 108    |
| 194         | -7              | 11/30/2009                 |                | Rx        | 68382005401 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                     | PDTS   | 109    |
| 195         | -6              | 12/01/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.) | PDTS   | 110    |

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|-------------|-----------------|-----------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 196         | -4              | 12/03/2009                  |                | Dx        | 2841  |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                  | TEDN   | 111    |
| 197         | -4              | 12/03/2009                  |                | Dx        | 5569  |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                  | TEDN   | 111    |
| 198         | -4              | 12/03/2009                  |                | Px        | 96372 |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                  | TEDN   | 111    |
| 199         | -4              | 12/03/2009                  |                | Px        | J0885 |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                  | TEDN   | 112    |
| 200         | -1              | 12/06/2009                  |                | Dx        | 78650 |     | Radio              | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 116    |
| 201         | -1              | 12/06/2009                  |                | Px        | 71010 |     | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 116    |
| 202         | -1              | 12/06/2009                  |                | Dx        | 78650 |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 117    |
| 203         | -1              | 12/06/2009                  |                | Dx        | 5859  |     | Grppract           | 2     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 117    |
| 204         | -1              | 12/06/2009                  |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 117    |
| 205         | -1              | 12/06/2009                  |                | Dx        | 4019  |     | Grppract           | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 117    |
| 206         | -1              | 12/06/2009                  |                | Dx        | 2449  |     | Grppract           | 5     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 117    |
| 207         | -1              | 12/06/2009                  |                | Dx        | 34590 |     | Grppract           | 6     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                  | TEDN   | 117    |
| 208         | -1              | 12/06/2009                  |                | Dx        | V5861 |     | Grppract           | 7     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 117    |
| 209         | -1              | 12/06/2009                  |                | Dx        | V5869 |     | Grppract           | 8     | Encounter Long Term Use Oth Drugs         |                        |             |     |                  | TEDN   | 117    |
| 210         | -1              | 12/06/2009                  |                | Px        | 93010 |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 117    |
| 211         | -1              | 12/06/2009                  |                | Dx        | 78650 |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 118    |
| 212         | -1              | 12/06/2009                  |                | Dx        | 5859  |     | Facility           | 2     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 118    |
| 213         | -1              | 12/06/2009                  |                | Dx        | 42731 |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 118    |
| 214         | -1              | 12/06/2009                  |                | Dx        | 4019  |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 118    |
| 215         | -1              | 12/06/2009                  |                | Dx        | 2449  |     | Facility           | 5     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 118    |
| 216         | -1              | 12/06/2009                  |                | Dx        | 34590 |     | Facility           | 6     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                  | TEDN   | 118    |
| 217         | -1              | 12/06/2009                  |                | Dx        | V5861 |     | Facility           | 7     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 118    |
| 218         | -1              | 12/06/2009                  |                | Dx        | V5869 |     | Facility           | 8     | Encounter Long Term Use Oth Drugs         |                        |             |     |                  | TEDN   | 118    |
| 219         | -1              | 12/06/2009                  |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 118    |
| 220         | -1              | 12/06/2009                  |                | Px        | 71010 |     | Facility           | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 119    |
| 221         | -1              | 12/06/2009                  |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 120    |
| 222         | -1              | 12/06/2009                  |                | Px        | 82553 |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                  | TEDN   | 121    |
| 223         | -1              | 12/06/2009                  |                | Px        | 83735 |     | Facility           | 1     | Magnesium                                 |                        |             |     |                  | TEDN   | 122    |
| 224         | -1              | 12/06/2009                  |                | Px        | 84484 |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                  | TEDN   | 123    |
| 225         | -1              | 12/06/2009                  |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 124    |
| 226         | -1              | 12/06/2009                  |                | Px        | 85378 |     | Facility           | 1     | Fibrin Dgradj Products D-Dimer Qual/Semiq |                        |             |     |                  | TEDN   | 125    |
| 227         | -1              | 12/06/2009                  |                | Px        | 85610 |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 126    |
| 228         | -1              | 12/06/2009                  |                | Px        | 93005 |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                  | TEDN   | 127    |
| 229         | -1              | 12/06/2009                  |                | Px        | 99070 |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                  | TEDN   | 128    |
| 230         | -1              | 12/06/2009                  |                | Px        | 99284 |     | Facility           | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                  | TEDN   | 129    |
| 231         | -1              | 12/06/2009                  |                | Px        | 99291 |     | Facility           | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 130    |
| 232         | -1              | 12/06/2009                  |                | Px        | 99292 |     | Facility           | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 131    |
| 233         | -1              | 12/06/2009                  |                | Px        | 99499 |     | Facility           | 1     | Unlisted Evaluation And Management Servic |                        |             |     |                  | TEDN   | 132    |
| 234         | -1              | 12/06/2009                  |                | Px        | A0425 |     | Facility           | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 133    |

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|-------------|-----------------|----------------------------|----------------|-----------|------------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 235         | -1              | 12/06/2009                 |                | Px        | A0426            |      | Facility           | 1     | Als 1                                     |                        |             |     |                                | TEDN   | 134    |
| 236         | -1              | 12/06/2009                 |                | Dx        | 42731            | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 113    |
| 237         | -1              | 12/06/2009                 |                | Px        | 93010            | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                                | TEDN   | 113    |
| 238         | -1              | 12/06/2009                 |                | Px        | 93306            | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                                | TEDN   | 114    |
| 239         | -1              | 12/06/2009                 |                | Px        | 99221            | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 30 Minutes      |                        |             |     |                                | TEDN   | 115    |
| 241         | 0               | 12/07/2009                 |                | Dx        | 4240             | Inpt | Cardvasc           | 1     | Mitral Valve Disorders                    |                        |             |     |                                | TEDN   | 136    |
| 242         | 0               | 12/07/2009                 |                | Dx        | 78659            | Inpt | Cardvasc           | 2     | Other Chest Pain                          |                        |             |     |                                | TEDN   | 136    |
| 243         | 0               | 12/07/2009                 |                | Px        | 99238            | Inpt | Cardvasc           | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                                | TEDN   | 136    |
| 240         | 0               | 12/07/2009                 | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | INITIAL FILL                   | PDTS   | 135    |
| 244         | 7               | 12/14/2009                 |                | Dx        | 42731            |      | Grpract            | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 137    |
| 245         | 7               | 12/14/2009                 |                | Dx        | 2720             |      | Grpract            | 2     | Pure Hypercholesterolemia                 |                        |             |     |                                | TEDN   | 137    |
| 246         | 7               | 12/14/2009                 |                | Dx        | 2449             |      | Grpract            | 3     | Uns Hypothyroidism                        |                        |             |     |                                | TEDN   | 137    |
| 247         | 7               | 12/14/2009                 |                | Px        | 99499            |      | Grpract            | 1     | Unlisted Evaluation And Management Servic |                        |             |     |                                | TEDN   | 137    |
| 248         | 10              | 12/17/2009                 |                | Dx        | 2841             |      | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 138    |
| 249         | 10              | 12/17/2009                 |                | Dx        | 5569             |      | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 138    |
| 250         | 10              | 12/17/2009                 |                | Dx        | 2859             |      | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 138    |
| 251         | 10              | 12/17/2009                 |                | Px        | 96372            |      | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 138    |
| 252         | 10              | 12/17/2009                 |                | Px        | J0885            |      | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 139    |
| 253         | 12              | 12/19/2009                 |                | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | REFILL                         | PDTS   | 140    |
| 254         | 12              | 12/19/2009                 |                | Rx        | 24658021310      |      |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 141    |
| 255         | 12              | 12/19/2009                 |                | Rx        | 00781518201      |      |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 142    |
| 256         | 21              | 12/28/2009                 |                | Dx        | 42731            |      | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 143    |
| 257         | 21              | 12/28/2009                 |                | Dx        | V5869            |      | Cardvasc           | 2     | Encounter Long Term Use Oth Drugs         |                        |             |     |                                | TEDN   | 143    |
| 258         | 21              | 12/28/2009                 |                | Px        | 99212            |      | Cardvasc           | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                | TEDN   | 143    |
| 259         | 33              | 01/09/2010                 |                | Rx        | 49884040510      |      |                    |       |                                           | Metoprolol Succinate   | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 144    |
| 260         | 34              | 01/10/2010                 |                | Rx        | 00074431730      |      |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 145    |
| 261         | 35              | 01/11/2010                 |                | Rx        | 49884040501      |      |                    |       |                                           | Metoprolol Succinate   | 30          | 90  | Tablet, Sustained Release 24hr | PDTS   | 146    |
| 262         | 42              | 01/18/2010                 |                | Rx        | 62175011843      |      |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 147    |
| 263         | 42              | 01/18/2010                 |                | Rx        | 00228266650      |      |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 148    |
| 264         | 45              | 01/21/2010                 |                | Dx        | 5853             |      | Gp                 | 1     | Chronic Kidney Disease Stage iii          |                        |             |     |                                | TEDN   | 149    |
| 265         | 45              | 01/21/2010                 |                | Dx        | 2859             |      | Gp                 | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 149    |
| 266         | 45              | 01/21/2010                 |                | Dx        | 58881            |      | Gp                 | 3     | Sec Hyperparathyroidism Renal             |                        |             |     |                                | TEDN   | 149    |
| 267         | 45              | 01/21/2010                 |                | Dx        | 4011             |      | Gp                 | 4     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 149    |
| 268         | 45              | 01/21/2010                 |                | Px        | 99214            |      | Gp                 | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 149    |
| 269         | 45              | 01/21/2010                 |                | Px        | 99284            |      | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                                | TEDN   | 150    |
| 270         | 45              | 01/21/2010                 |                | Dx        | 7944             |      | Facility           | 1     | Abnormal Kidney Funct Study               |                        |             |     |                                | TEDN   | 151    |
| 271         | 45              | 01/21/2010                 |                | Dx        | 5939             |      | Facility           | 2     | Uns Disorder Kidney/Ureter                |                        |             |     |                                | TEDN   | 151    |
| 272         | 45              | 01/21/2010                 |                | Dx        | 2449             |      | Facility           | 3     | Uns Hypothyroidism                        |                        |             |     |                                | TEDN   | 151    |

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|-------------|-----------------|-----------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 273         | 45              | 01/21/2010                  |                | Dx        | V8801 |     | Facility           | 4     | Acq Absence Both Cervix Uterus            |                        |             |     |                  | TEDN   | 151    |
| 274         | 45              | 01/21/2010                  |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 151    |
| 275         | 45              | 01/21/2010                  |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 152    |
| 276         | 45              | 01/21/2010                  |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 153    |
| 277         | 45              | 01/21/2010                  |                | Px        | 99283 |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                  | TEDN   | 154    |
| 278         | 50              | 01/26/2010                  |                | Dx        | 78900 |     | Radio              | 1     | Abdominal Pain Uns Site                   |                        |             |     |                  | TEDN   | 155    |
| 279         | 50              | 01/26/2010                  |                | Dx        | V6709 |     | Radio              | 2     | Follow-Up Follow Oth Surgery              |                        |             |     |                  | TEDN   | 155    |
| 280         | 50              | 01/26/2010                  |                | Px        | 71010 |     | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 155    |
| 281         | 50              | 01/26/2010                  |                | Px        | 72192 |     | Radio              | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 156    |
| 282         | 50              | 01/26/2010                  |                | Px        | 74150 |     | Radio              | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 157    |
| 283         | 50              | 01/26/2010                  |                | Dx        | 78900 |     | Facility           | 1     | Abdominal Pain Uns Site                   |                        |             |     |                  | TEDN   | 159    |
| 284         | 50              | 01/26/2010                  |                | Dx        | 4019  |     | Facility           | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 159    |
| 285         | 50              | 01/26/2010                  |                | Dx        | 53081 |     | Facility           | 3     | Esophageal Reflux                         |                        |             |     |                  | TEDN   | 159    |
| 286         | 50              | 01/26/2010                  |                | Dx        | 2724  |     | Facility           | 4     | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDN   | 159    |
| 287         | 50              | 01/26/2010                  |                | Dx        | 42731 |     | Facility           | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 159    |
| 288         | 50              | 01/26/2010                  |                | Dx        | 2859  |     | Facility           | 6     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 159    |
| 289         | 50              | 01/26/2010                  |                | Dx        | 5859  |     | Facility           | 7     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 159    |
| 290         | 50              | 01/26/2010                  |                | Dx        | V442  |     | Facility           | 8     | Ileostomy Status                          |                        |             |     |                  | TEDN   | 159    |
| 291         | 50              | 01/26/2010                  |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 159    |
| 292         | 50              | 01/26/2010                  |                | Px        | 71010 |     | Facility           | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 160    |
| 293         | 50              | 01/26/2010                  |                | Px        | 72192 |     | Facility           | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 161    |
| 294         | 50              | 01/26/2010                  |                | Px        | 74150 |     | Facility           | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 162    |
| 295         | 50              | 01/26/2010                  |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 163    |
| 296         | 50              | 01/26/2010                  |                | Px        | 81001 |     | Facility           | 1     | Urnl Dip Stick/Tablet Reagent Auto Micro  |                        |             |     |                  | TEDN   | 164    |
| 297         | 50              | 01/26/2010                  |                | Px        | 82150 |     | Facility           | 1     | Amylase                                   |                        |             |     |                  | TEDN   | 165    |
| 298         | 50              | 01/26/2010                  |                | Px        | 83690 |     | Facility           | 1     | Lipase                                    |                        |             |     |                  | TEDN   | 166    |
| 299         | 50              | 01/26/2010                  |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 167    |
| 300         | 50              | 01/26/2010                  |                | Px        | 85610 |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 168    |
| 301         | 50              | 01/26/2010                  |                | Px        | 85730 |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                  | TEDN   | 169    |
| 302         | 50              | 01/26/2010                  |                | Px        | 96361 |     | Facility           | 1     | Iv Infusion Hydration Each Additional Hou |                        |             |     |                  | TEDN   | 170    |
| 303         | 50              | 01/26/2010                  |                | Px        | 96374 |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbst |                        |             |     |                  | TEDN   | 171    |
| 304         | 50              | 01/26/2010                  |                | Px        | 96375 |     | Facility           | 1     | Therapeutic Injection Iv Push Each New Dr |                        |             |     |                  | TEDN   | 172    |
| 305         | 50              | 01/26/2010                  |                | Px        | 96376 |     | Facility           | 1     | Ther Proph/Dx Njx Ea Seq Iv Push Sbst/Dr  |                        |             |     |                  | TEDN   | 173    |
| 306         | 50              | 01/26/2010                  |                | Px        | 99070 |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                  | TEDN   | 174    |
| 307         | 50              | 01/26/2010                  |                | Px        | 99285 |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 175    |
| 308         | 50              | 01/26/2010                  |                | Px        | 99499 |     | Facility           | 1     | Unlisted Evaluation And Management Servc  |                        |             |     |                  | TEDN   | 176    |
| 309         | 50              | 01/26/2010                  |                | Px        | A0425 |     | Facility           | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 177    |
| 310         | 50              | 01/26/2010                  |                | Px        | A0426 |     | Facility           | 1     | Als 1                                     |                        |             |     |                  | TEDN   | 178    |
| 311         | 50              | 01/26/2010                  | 02/03/2010     | Dx        | 56081 |     |                    | 1     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDI   | 179    |

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|-------------|-----------------|----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 312         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 0389  |      |                    | 2     | Uns Septicemia                            |                        |             |     |                  | TEDI   | 179    |
| 313         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 99592 |      |                    | 3     | Severe Sepsis                             |                        |             |     |                  | TEDI   | 179    |
| 314         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 78552 |      |                    | 4     | Septic Shock                              |                        |             |     |                  | TEDI   | 179    |
| 315         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 5849  |      |                    | 5     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDI   | 179    |
| 316         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 570   |      |                    | 6     | Acute/Subacute Necrosis Liver             |                        |             |     |                  | TEDI   | 179    |
| 317         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 34831 |      |                    | 7     | Metabolic Encephalopathy                  |                        |             |     |                  | TEDI   | 179    |
| 318         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 51881 |      |                    | 8     | Respiratory Failure                       |                        |             |     |                  | TEDI   | 179    |
| 319         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 42821 |      |                    | 9     | Acute Systolic Heart Failure              |                        |             |     |                  | TEDI   | 179    |
| 320         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 5459  |      |                    | 1     | Other Periton Adhesiolysis                |                        |             |     |                  | TEDI   | 179    |
| 321         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9604  |      |                    | 2     | Insertion Endotracheal Tube               |                        |             |     |                  | TEDI   | 179    |
| 322         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9672  |      |                    | 3     | Cont Inv Mec Ven 96+ Hrs                  |                        |             |     |                  | TEDI   | 179    |
| 323         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 3891  |      |                    | 4     | Arterial Catheterization                  |                        |             |     |                  | TEDI   | 179    |
| 324         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9904  |      |                    | 5     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 179    |
| 325         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 3895  |      |                    | 6     | Ven Cath Renal Dialysis                   |                        |             |     |                  | TEDI   | 179    |
| 326         | 50              | 01/26/2010                 |                | Dx        | 5609  | Inpt | Grpract            | 1     | Uns Intestinal Obstruction                |                        |             |     |                  | TEDN   | 158    |
| 327         | 50              | 01/26/2010                 |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 158    |
| 328         | 50              | 01/26/2010                 |                | Dx        | 42731 | Inpt | Grpract            | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 158    |
| 329         | 50              | 01/26/2010                 |                | Dx        | 2449  | Inpt | Grpract            | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 158    |
| 330         | 50              | 01/26/2010                 |                | Px        | 99223 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 158    |
| 331         | 51              | 01/27/2010                 |                | Dx        | 78907 | Inpt | Gensurg            | 1     | Abdominal Pain Generalized                |                        |             |     |                  | TEDN   | 180    |
| 332         | 51              | 01/27/2010                 |                | Dx        | 56081 | Inpt | Gensurg            | 2     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDN   | 180    |
| 333         | 51              | 01/27/2010                 |                | Dx        | 4460  | Inpt | Gensurg            | 3     | Polyarteritis Nodosa                      |                        |             |     |                  | TEDN   | 180    |
| 334         | 51              | 01/27/2010                 |                | Px        | 44604 | Inpt | Gensurg            | 1     | Sutr Lg Intestine 1/Mult Perforat W/O Col |                        |             |     |                  | TEDN   | 180    |
| 335         | 51              | 01/27/2010                 |                | Px        | 99232 | Inpt | Gensurg            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 181    |
| 336         | 51              | 01/27/2010                 |                | Dx        | 42761 | Inpt | Cardvasc           | 1     | Supraventricular Premature Beats          |                        |             |     |                  | TEDN   | 182    |
| 337         | 51              | 01/27/2010                 |                | Dx        | 42731 | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 182    |
| 338         | 51              | 01/27/2010                 |                | Dx        | 79431 | Inpt | Cardvasc           | 3     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 182    |
| 339         | 51              | 01/27/2010                 |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 182    |
| 340         | 51              | 01/27/2010                 |                | Dx        | 5609  | Inpt | Radio              | 1     | Uns Intestinal Obstruction                |                        |             |     |                  | TEDN   | 183    |
| 341         | 51              | 01/27/2010                 |                | Px        | 74022 | Inpt | Radio              | 1     | Radex Abd Compl Aqt Abd W/S/E/D Views 1 V |                        |             |     |                  | TEDN   | 183    |
| 342         | 51              | 01/27/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 184    |
| 343         | 51              | 01/27/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 185    |
| 344         | 51              | 01/27/2010                 |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 186    |
| 345         | 51              | 01/27/2010                 |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 186    |
| 346         | 51              | 01/27/2010                 |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 186    |
| 347         | 51              | 01/27/2010                 |                | Px        | 99233 | Inpt | Nephrr             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 186    |
| 348         | 51              | 01/27/2010                 |                | Dx        | 56081 | Inpt | Grpract            | 1     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDN   | 187    |
| 349         | 51              | 01/27/2010                 |                | Px        | 00840 | Inpt | Grpract            | 1     | Anesthesia Intraperitoneal Lower Abd W/La |                        |             |     |                  | TEDN   | 187    |

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|-------------|-----------------|-----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 350         | 51              | 01/27/2010                  |                | Px        | 99223 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 188    |
| 351         | 52              | 01/28/2010                  |                | Dx        | 42761 | Inpt | Cardvasc           | 1     | Supraventricular Premature Beats          |                        |             |     |                  | TEDN   | 189    |
| 352         | 52              | 01/28/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 189    |
| 353         | 52              | 01/28/2010                  |                | Dx        | 79431 | Inpt | Cardvasc           | 3     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 189    |
| 354         | 52              | 01/28/2010                  |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 189    |
| 355         | 52              | 01/28/2010                  |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 190    |
| 356         | 52              | 01/28/2010                  |                | Dx        | 0389  | Inpt | Radio              | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 191    |
| 357         | 52              | 01/28/2010                  |                | Dx        | 99592 | Inpt | Radio              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 191    |
| 358         | 52              | 01/28/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 191    |
| 359         | 52              | 01/28/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 192    |
| 360         | 52              | 01/28/2010                  |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 193    |
| 361         | 52              | 01/28/2010                  |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 193    |
| 362         | 52              | 01/28/2010                  |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 193    |
| 363         | 52              | 01/28/2010                  |                | Px        | 99233 | Inpt | Nephrr             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 193    |
| 364         | 52              | 01/28/2010                  |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 194    |
| 365         | 52              | 01/28/2010                  |                | Dx        | 2752  | Inpt | Grpract            | 2     | Disorders Magnesium Metabolism            |                        |             |     |                  | TEDN   | 194    |
| 366         | 52              | 01/28/2010                  |                | Dx        | 27541 | Inpt | Grpract            | 3     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 194    |
| 367         | 52              | 01/28/2010                  |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 194    |
| 368         | 52              | 01/28/2010                  |                | Px        | 93010 | Inpt | Grpract            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 195    |
| 369         | 52              | 01/28/2010                  |                | Px        | 31500 | Inpt | Grpract            | 1     | Intubation Endotracheal Emergency Procedu |                        |             |     |                  | TEDN   | 196    |
| 370         | 52              | 01/28/2010                  |                | Px        | 99291 | Inpt | Grpract            | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 197    |
| 371         | 53              | 01/29/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 198    |
| 372         | 53              | 01/29/2010                  |                | Dx        | 7905  | Inpt | Cardvasc           | 2     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 198    |
| 373         | 53              | 01/29/2010                  |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 198    |
| 374         | 53              | 01/29/2010                  |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 199    |
| 375         | 53              | 01/29/2010                  |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 200    |
| 376         | 53              | 01/29/2010                  |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 200    |
| 377         | 53              | 01/29/2010                  |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 200    |
| 378         | 53              | 01/29/2010                  |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 200    |
| 379         | 53              | 01/29/2010                  |                | Px        | 36620 | Inpt | Pulmo              | 1     | Artl Cathj/Cannulj Mntr/Transfusion Spx P |                        |             |     |                  | TEDN   | 200    |
| 380         | 53              | 01/29/2010                  |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 201    |
| 381         | 53              | 01/29/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 201    |
| 382         | 53              | 01/29/2010                  |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 202    |
| 383         | 53              | 01/29/2010                  |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 202    |
| 384         | 53              | 01/29/2010                  |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 202    |
| 385         | 53              | 01/29/2010                  |                | Px        | 36556 | Inpt | Nephrr             | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 202    |
| 386         | 53              | 01/29/2010                  |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 203    |
| 387         | 53              | 01/29/2010                  |                | Dx        | 2851  | Inpt | Grpract            | 2     | Acute Posthemorrhagic Anemia              |                        |             |     |                  | TEDN   | 203    |



Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code  | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 388         | 53              | 01/29/2010                  |                | Px        | 99231 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 203    |
| 389         | 54              | 01/30/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 204    |
| 390         | 54              | 01/30/2010                  |                | Dx        | 7905  | Inpt | Cardvasc           | 2     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 204    |
| 391         | 54              | 01/30/2010                  |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 204    |
| 392         | 54              | 01/30/2010                  |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 205    |
| 393         | 54              | 01/30/2010                  |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 205    |
| 394         | 54              | 01/30/2010                  |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 205    |
| 395         | 54              | 01/30/2010                  |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 205    |
| 396         | 54              | 01/30/2010                  |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 205    |
| 397         | 54              | 01/30/2010                  |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 206    |
| 398         | 54              | 01/30/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 206    |
| 399         | 54              | 01/30/2010                  |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 207    |
| 400         | 54              | 01/30/2010                  |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 207    |
| 401         | 54              | 01/30/2010                  |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 207    |
| 402         | 54              | 01/30/2010                  |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 207    |
| 403         | 54              | 01/30/2010                  |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 208    |
| 404         | 54              | 01/30/2010                  |                | Dx        | 2851  | Inpt | Grpract            | 2     | Acute Posthemorrhagic Anemia              |                        |             |     |                  | TEDN   | 208    |
| 405         | 54              | 01/30/2010                  |                | Px        | 99231 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 208    |
| 406         | 55              | 01/31/2010                  |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 209    |
| 407         | 55              | 01/31/2010                  |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 209    |
| 408         | 55              | 01/31/2010                  |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 209    |
| 409         | 55              | 01/31/2010                  |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 209    |
| 410         | 55              | 01/31/2010                  |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 209    |
| 411         | 55              | 01/31/2010                  |                | Dx        | 43491 | Inpt | Radio              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 210    |
| 412         | 55              | 01/31/2010                  |                | Px        | 70450 | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 210    |
| 413         | 55              | 01/31/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 211    |
| 414         | 55              | 01/31/2010                  |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 212    |
| 415         | 55              | 01/31/2010                  |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 212    |
| 416         | 55              | 01/31/2010                  |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 212    |
| 417         | 55              | 01/31/2010                  |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 212    |
| 418         | 55              | 01/31/2010                  |                | Dx        | 34830 | Inpt | Grpract            | 1     | Encephalopathy Unspecified                |                        |             |     |                  | TEDN   | 213    |
| 419         | 55              | 01/31/2010                  |                | Px        | 99223 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 213    |
| 420         | 55              | 01/31/2010                  |                | Px        | 95822 | Inpt | Grpract            | 1     | Electroencephalogram Rec Coma/Sleep Only  |                        |             |     |                  | TEDN   | 214    |
| 421         | 56              | 02/01/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 215    |
| 422         | 56              | 02/01/2010                  |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 215    |
| 423         | 56              | 02/01/2010                  |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 216    |
| 424         | 56              | 02/01/2010                  |                | Dx        | 43491 | Inpt | Neuro              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 217    |
| 425         | 56              | 02/01/2010                  |                | Dx        | 34591 | Inpt | Neuro              | 2     | Uns Epilepsy W Intract Epilepsy           |                        |             |     |                  | TEDN   | 217    |

Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code  | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 426         | 56              | 02/01/2010                 |                | Px        | 99223 | Inpt | Neuro              | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 217    |
| 427         | 56              | 02/01/2010                 |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 218    |
| 428         | 56              | 02/01/2010                 |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 218    |
| 429         | 56              | 02/01/2010                 |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 218    |
| 430         | 56              | 02/01/2010                 |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 218    |
| 431         | 56              | 02/01/2010                 |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 218    |
| 432         | 56              | 02/01/2010                 |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 219    |
| 433         | 56              | 02/01/2010                 |                | Dx        | 2774  | Inpt | Radio              | 2     | Disorders Bilirubin Excretion             |                        |             |     |                  | TEDN   | 219    |
| 434         | 56              | 02/01/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 219    |
| 435         | 56              | 02/01/2010                 |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 220    |
| 436         | 56              | 02/01/2010                 |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 221    |
| 437         | 56              | 02/01/2010                 |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 221    |
| 438         | 56              | 02/01/2010                 |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 221    |
| 439         | 56              | 02/01/2010                 |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 221    |
| 440         | 56              | 02/01/2010                 |                | Dx        | 5679  | Inpt | Grppract           | 1     | Uns Peritonitis                           |                        |             |     |                  | TEDN   | 222    |
| 441         | 56              | 02/01/2010                 |                | Px        | 99223 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 222    |
| 442         | 57              | 02/02/2010                 |                | Dx        | 43491 | Inpt | Neuro              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 223    |
| 443         | 57              | 02/02/2010                 |                | Dx        | 34591 | Inpt | Neuro              | 2     | Uns Epilepsy W Intract Epilepsy           |                        |             |     |                  | TEDN   | 223    |
| 444         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Neuro              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 223    |
| 445         | 57              | 02/02/2010                 |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 224    |
| 446         | 57              | 02/02/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 224    |
| 447         | 57              | 02/02/2010                 |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 225    |
| 448         | 57              | 02/02/2010                 |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 225    |
| 449         | 57              | 02/02/2010                 |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 225    |
| 450         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 225    |
| 451         | 57              | 02/02/2010                 |                | Dx        | 5679  | Inpt | Grppract           | 1     | Uns Peritonitis                           |                        |             |     |                  | TEDN   | 226    |
| 452         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 226    |
| 453         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 227    |

End of Profile

Patient ID: SLD-0126

Age: 81 Gender: F Indexdate: 06/23/2012 Event Date: 07/17/2013 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation             | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 1           | -362            | 06/27/2011                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 1      |
| 2           | -347            | 07/12/2011                     |                | Dx        | 4512        |     | Intmed             | 1     | Uns Phlebitis Lower Limbs                 |                        |             |     |                              | TEDN   | 2      |
| 3           | -347            | 07/12/2011                     |                | Px        | 99220       |     | Intmed             | 1     | Initial Observation Care/Day High Severit |                        |             |     |                              | TEDN   | 2      |
| 4           | -347            | 07/12/2011                     |                | Dx        | 4928        |     | Radio              | 1     | Other Emphysema                           |                        |             |     |                              | TEDN   | 3      |
| 5           | -347            | 07/12/2011                     |                | Px        | 71020       |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                              | TEDN   | 3      |
| 6           | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Radio              | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 4      |
| 7           | -347            | 07/12/2011                     |                | Dx        | 45342       |     | Radio              | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 4      |
| 8           | -347            | 07/12/2011                     |                | Dx        | 45119       |     | Radio              | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 4      |
| 9           | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Radio              | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 4      |
| 10          | -347            | 07/12/2011                     |                | Px        | 93970       |     | Radio              | 1     | Dup-Scan Xtr Veins Complete Bilateral Stu |                        |             |     |                              | TEDN   | 4      |
| 11          | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Facility           | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 5      |
| 12          | -347            | 07/12/2011                     |                | Dx        | 45342       |     | Facility           | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 5      |
| 13          | -347            | 07/12/2011                     |                | Dx        | 45119       |     | Facility           | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 5      |
| 14          | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Facility           | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 5      |
| 15          | -347            | 07/12/2011                     |                | Dx        | 71690       |     | Facility           | 5     | Uns Arthropathy Site Uns                  |                        |             |     |                              | TEDN   | 5      |
| 16          | -347            | 07/12/2011                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension        |                        |             |     |                              | TEDN   | 5      |
| 17          | -347            | 07/12/2011                     |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                              | TEDN   | 5      |
| 18          | -347            | 07/12/2011                     |                | Dx        | 78039       |     | Facility           | 8     | Other Convulsions                         |                        |             |     |                              | TEDN   | 5      |
| 19          | -347            | 07/12/2011                     |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                              | TEDN   | 5      |
| 20          | -347            | 07/12/2011                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                              | TEDN   | 6      |
| 21          | -347            | 07/12/2011                     |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                              | TEDN   | 7      |
| 22          | -347            | 07/12/2011                     |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                              | TEDN   | 8      |
| 23          | -347            | 07/12/2011                     |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 9      |
| 24          | -347            | 07/12/2011                     |                | Px        | 85730       |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                              | TEDN   | 10     |
| 25          | -347            | 07/12/2011                     |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                              | TEDN   | 11     |
| 26          | -347            | 07/12/2011                     |                | Px        | 93970       |     | Facility           | 1     | Dup-Scan Xtr Veins Complete Bilateral Stu |                        |             |     |                              | TEDN   | 12     |
| 27          | -347            | 07/12/2011                     |                | Px        | 96361       |     | Facility           | 1     | Iv Infusion Hydration Each Additional Hou |                        |             |     |                              | TEDN   | 13     |
| 28          | -347            | 07/12/2011                     |                | Px        | 96365       |     | Facility           | 1     | Iv Infusion Therapy/Prophylaxis /Dx 1st T |                        |             |     |                              | TEDN   | 14     |
| 29          | -347            | 07/12/2011                     |                | Px        | 96372       |     | Facility           | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                              | TEDN   | 15     |
| 30          | -347            | 07/12/2011                     |                | Px        | 96375       |     | Facility           | 1     | Therapeutic Injection Iv Push Each New Dr |                        |             |     |                              | TEDN   | 16     |
| 31          | -347            | 07/12/2011                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                              | TEDN   | 17     |
| 32          | -347            | 07/12/2011                     |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                              | TEDN   | 18     |
| 33          | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 19     |
| 34          | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Grppract           | 2     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 19     |
| 35          | -347            | 07/12/2011                     |                | Dx        | 45340       |     | Grppract           | 3     | Ac Emb/Throm Uns Deep Ves Lower Ext       |                        |             |     |                              | TEDN   | 19     |
| 36          | -347            | 07/12/2011                     |                | Px        | 93010       |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds l&r Only   |                        |             |     |                              | TEDN   | 19     |
| 37          | -347            | 07/12/2011                     |                | Px        | 99285       |     | Grppract           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                              | TEDN   | 20     |
| 38          | -346            | 07/13/2011                     |                | Dx        | 6826        |     | Facility           | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 25     |
| 39          | -346            | 07/13/2011                     |                | Dx        | 45342       |     | Facility           | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 25     |
| 40          | -346            | 07/13/2011                     |                | Dx        | 45119       |     | Facility           | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 25     |
| 41          | -346            | 07/13/2011                     |                | Dx        | 78650       |     | Facility           | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 25     |
| 42          | -346            | 07/13/2011                     |                | Dx        | 71690       |     | Facility           | 5     | Uns Arthropathy Site Uns                  |                        |             |     |                              | TEDN   | 25     |
| 43          | -346            | 07/13/2011                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension        |                        |             |     |                              | TEDN   | 25     |
| 44          | -346            | 07/13/2011                     |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                              | TEDN   | 25     |
| 45          | -346            | 07/13/2011                     |                | Dx        | 78039       |     | Facility           | 8     | Other Convulsions                         |                        |             |     |                              | TEDN   | 25     |
| 46          | -346            | 07/13/2011                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                              | TEDN   | 25     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 47          | -346            | 07/13/2011                     |                | Px        | 85025       |      | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                              | TEDN   | 26     |
| 48          | -346            | 07/13/2011                     |                | Px        | 99070       |      | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                              | TEDN   | 27     |
| 49          | -346            | 07/13/2011                     |                | Rx        | 42043014105 |      |                    |       |                                           | Cephalexin             | 10          | 30  | Capsule (Hard, Soft, Etc.)   | PDTS   | 21     |
| 50          | -346            | 07/13/2011                     |                | Rx        | 00555083305 |      |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                       | PDTS   | 22     |
| 51          | -346            | 07/13/2011                     |                | Rx        | 00781311968 |      |                    |       |                                           | Enoxaparin Sodium      | 7           | 11  | Disposable Syringe (MI)      | PDTS   | 23     |
| 52          | -346            | 07/13/2011                     |                | Rx        | 00378520905 |      |                    |       |                                           | Amlodipine Besylate    | 30          | 30  | Tablet                       | PDTS   | 24     |
| 53          | -345            | 07/14/2011                     |                | Dx        | 45111       |      | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 28     |
| 54          | -345            | 07/14/2011                     |                | Dx        | 7197        |      | Intmed             | 2     | Difficulty In Walking                     |                        |             |     |                              | TEDN   | 28     |
| 55          | -345            | 07/14/2011                     |                | Dx        | 78079       |      | Intmed             | 3     | Other Malaise And Fatigue                 |                        |             |     |                              | TEDN   | 28     |
| 56          | -345            | 07/14/2011                     |                | Px        | G0180       |      | Intmed             | 1     | Md Certification Hha Patient              |                        |             |     |                              | TEDN   | 28     |
| 57          | -337            | 07/22/2011                     |                | Dx        | 5693        |      | Gp                 | 1     | Hemorrhage Rectum/Anus                    |                        |             |     |                              | TEDN   | 30     |
| 58          | -337            | 07/22/2011                     |                | Dx        | 59970       |      | Gp                 | 2     | Hematuria Unspecified                     |                        |             |     |                              | TEDN   | 30     |
| 59          | -337            | 07/22/2011                     |                | Dx        | 45342       |      | Gp                 | 3     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 30     |
| 60          | -337            | 07/22/2011                     |                | Dx        | 2869        |      | Gp                 | 4     | Oth/Uns Coagulation Defects               |                        |             |     |                              | TEDN   | 30     |
| 61          | -337            | 07/22/2011                     |                | Px        | 99291       |      | Gp                 | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                              | TEDN   | 30     |
| 62          | -337            | 07/22/2011                     |                | Dx        | 3489        | Inpt | Radio              | 1     | Unspecified Condition Of Brain            |                        |             |     |                              | TEDN   | 29     |
| 63          | -337            | 07/22/2011                     |                | Dx        | 7840        | Inpt | Radio              | 2     | Headache                                  |                        |             |     |                              | TEDN   | 29     |
| 64          | -337            | 07/22/2011                     |                | Dx        | 2989        | Inpt | Radio              | 3     | Unspecified Psychosis                     |                        |             |     |                              | TEDN   | 29     |
| 65          | -337            | 07/22/2011                     |                | Px        | 70450       | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                              | TEDN   | 29     |
| 66          | -337            | 07/22/2011                     |                | Dx        | 5781        | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                              | TEDN   | 31     |
| 67          | -337            | 07/22/2011                     |                | Dx        | 56210       | Inpt | Gastro             | 2     | Diverticulosis Colon                      |                        |             |     |                              | TEDN   | 31     |
| 68          | -337            | 07/22/2011                     |                | Px        | 99222       | Inpt | Gastro             | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                              | TEDN   | 31     |
| 69          | -337            | 07/22/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 32     |
| 70          | -337            | 07/22/2011                     |                | Px        | 99223       | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                              | TEDN   | 32     |
| 71          | -336            | 07/23/2011                     |                | Dx        | 5781        | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                              | TEDN   | 33     |
| 72          | -336            | 07/23/2011                     |                | Dx        | 56210       | Inpt | Gastro             | 2     | Diverticulosis Colon                      |                        |             |     |                              | TEDN   | 33     |
| 73          | -336            | 07/23/2011                     |                | Px        | 45378       | Inpt | Gastro             | 1     | Colonoscopy Flx Dx W/Wo Collj Specimens   |                        |             |     |                              | TEDN   | 33     |
| 74          | -336            | 07/23/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 34     |
| 75          | -336            | 07/23/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 34     |
| 76          | -335            | 07/24/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 35     |
| 77          | -335            | 07/24/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 35     |
| 78          | -334            | 07/25/2011                     |                | Dx        | 56212       | Inpt | Gensurg            | 1     | Diverticulosis Colon W Hemorrhage         |                        |             |     |                              | TEDN   | 36     |
| 79          | -334            | 07/25/2011                     |                | Dx        | 4536        | Inpt | Gensurg            | 2     | Emb/Throm Superficial Lower Ext           |                        |             |     |                              | TEDN   | 36     |
| 80          | -334            | 07/25/2011                     |                | Dx        | 45351       | Inpt | Gensurg            | 3     | Ch Emb/Thr Prox Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 36     |
| 81          | -334            | 07/25/2011                     |                | Dx        | 59970       | Inpt | Gensurg            | 4     | Hematuria Unspecified                     |                        |             |     |                              | TEDN   | 36     |
| 82          | -334            | 07/25/2011                     |                | Px        | 93971       | Inpt | Gensurg            | 1     | Dup-Scan Xtr Veins Unilateral/Limited Stu |                        |             |     |                              | TEDN   | 36     |
| 83          | -334            | 07/25/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 37     |
| 84          | -334            | 07/25/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 37     |
| 85          | -333            | 07/26/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 38     |
| 86          | -333            | 07/26/2011                     |                | Px        | 99238       | Inpt | Intmed             | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                              | TEDN   | 38     |
| 87          | -323            | 08/05/2011                     |                | Rx        | 55111015810 |      |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 39     |
| 88          | -305            | 08/23/2011                     |                | Dx        | 79902       |      | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 40     |
| 89          | -305            | 08/23/2011                     |                | Px        | E0431       |      | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 40     |
| 90          | -305            | 08/23/2011                     |                | Px        | E1390       |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 41     |
| 91          | -304            | 08/24/2011                     |                | Rx        | 00054001725 |      |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 42     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|--------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 92          | -303            | 08/25/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 43     |
| 93          | -289            | 09/08/2011                     |                | Rx        | 00093714618 |     |                    |       |                                            | Azithromycin           | 5           | 6   | Tablet                       | PDTS   | 44     |
| 94          | -274            | 09/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 45     |
| 95          | -274            | 09/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 45     |
| 96          | -274            | 09/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 46     |
| 97          | -264            | 10/03/2011                     |                | Rx        | 33332001101 |     |                    |       |                                            | Afluria 2011-2012 (Pf) | 1           | 1   | Disposable Syringe (MI)      | PDTS   | 47     |
| 98          | -263            | 10/04/2011                     |                | Rx        | 55111015810 |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 48     |
| 99          | -261            | 10/06/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 49     |
| 100         | -260            | 10/07/2011                     |                | Rx        | 63304062210 |     |                    |       |                                            | Atenolol               | 90          | 180 | Tablet                       | PDTS   | 50     |
| 101         | -256            | 10/11/2011                     |                | Rx        | 68180075103 |     |                    |       |                                            | Amlodipine Besylate    | 90          | 90  | Tablet                       | PDTS   | 51     |
| 102         | -244            | 10/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 52     |
| 103         | -244            | 10/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 52     |
| 104         | -244            | 10/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 53     |
| 105         | -243            | 10/24/2011                     |                | Dx        | 56989       |     | Radio              | 1     | Other Disorders Intestines                 |                        |             |     |                              | TEDN   | 54     |
| 106         | -243            | 10/24/2011                     |                | Dx        | 78900       |     | Radio              | 2     | Abdominal Pain Uns Site                    |                        |             |     |                              | TEDN   | 54     |
| 107         | -243            | 10/24/2011                     |                | Px        | 74177       |     | Radio              | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                              | TEDN   | 54     |
| 108         | -243            | 10/24/2011                     |                | Dx        | 78901       |     | Gp                 | 1     | Abdom Pain R Upper Quad                    |                        |             |     |                              | TEDN   | 55     |
| 109         | -243            | 10/24/2011                     |                | Dx        | 78702       |     | Gp                 | 2     | Nausea Alone                               |                        |             |     |                              | TEDN   | 55     |
| 110         | -243            | 10/24/2011                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se  |                        |             |     |                              | TEDN   | 55     |
| 111         | -243            | 10/24/2011                     |                | Dx        | 78901       |     | Facility           | 1     | Abdom Pain R Upper Quad                    |                        |             |     |                              | TEDN   | 56     |
| 112         | -243            | 10/24/2011                     |                | Dx        | 78702       |     | Facility           | 2     | Nausea Alone                               |                        |             |     |                              | TEDN   | 56     |
| 113         | -243            | 10/24/2011                     |                | Dx        | 7962        |     | Facility           | 3     | Elevated Bp Reading Wo Htn Dx              |                        |             |     |                              | TEDN   | 56     |
| 114         | -243            | 10/24/2011                     |                | Dx        | 2720        |     | Facility           | 4     | Pure Hypercholesterolemia                  |                        |             |     |                              | TEDN   | 56     |
| 115         | -243            | 10/24/2011                     |                | Dx        | 7102        |     | Facility           | 5     | Sicca Syndrome                             |                        |             |     |                              | TEDN   | 56     |
| 116         | -243            | 10/24/2011                     |                | Dx        | 7291        |     | Facility           | 6     | Uns Myalgia/Myositis                       |                        |             |     |                              | TEDN   | 56     |
| 117         | -243            | 10/24/2011                     |                | Dx        | 33829       |     | Facility           | 7     | Other Chronic Pain                         |                        |             |     |                              | TEDN   | 56     |
| 118         | -243            | 10/24/2011                     |                | Dx        | V1251       |     | Facility           | 8     | History Venous Thrombosis/Embolism         |                        |             |     |                              | TEDN   | 56     |
| 119         | -243            | 10/24/2011                     |                | Px        | 74177       |     | Facility           | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                              | TEDN   | 56     |
| 120         | -243            | 10/24/2011                     |                | Px        | 80053       |     | Facility           | 1     | Comprehensive Metabolic Panel              |                        |             |     |                              | TEDN   | 57     |
| 121         | -243            | 10/24/2011                     |                | Px        | 81001       |     | Facility           | 1     | Urnl Dip Stick/Tablet Reagent Auto Micro   |                        |             |     |                              | TEDN   | 58     |
| 122         | -243            | 10/24/2011                     |                | Px        | 83690       |     | Facility           | 1     | Lipase                                     |                        |             |     |                              | TEDN   | 59     |
| 123         | -243            | 10/24/2011                     |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Diffrntl Wb |                        |             |     |                              | TEDN   | 60     |
| 124         | -243            | 10/24/2011                     |                | Px        | 96374       |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbst  |                        |             |     |                              | TEDN   | 61     |
| 125         | -243            | 10/24/2011                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above     |                        |             |     |                              | TEDN   | 62     |
| 126         | -243            | 10/24/2011                     |                | Px        | 99284       |     | Facility           | 1     | Emergency Department Visit High/Urgent Se  |                        |             |     |                              | TEDN   | 63     |
| 127         | -235            | 11/01/2011                     |                | Dx        | 4019        |     | Patho              | 1     | Unspecified Essential Hypertension         |                        |             |     |                              | TEDN   | 64     |
| 128         | -235            | 11/01/2011                     |                | Dx        | 2859        |     | Patho              | 2     | Anemia Unspecified                         |                        |             |     |                              | TEDN   | 64     |
| 129         | -235            | 11/01/2011                     |                | Dx        | 45340       |     | Patho              | 3     | Ac Emb/Throm Uns Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 64     |
| 130         | -235            | 11/01/2011                     |                | Px        | 85390       |     | Patho              | 1     | Fibrinolysins/Coagulopathy Screen Interp&  |                        |             |     |                              | TEDN   | 64     |
| 131         | -223            | 11/13/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 65     |
| 132         | -219            | 11/17/2011                     |                | Rx        | 00054001725 |     |                    |       |                                            | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 66     |
| 133         | -213            | 11/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 67     |
| 134         | -213            | 11/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 67     |
| 135         | -213            | 11/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 68     |
| 136         | -210            | 11/26/2011                     |                | Rx        | 55111015810 |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 69     |
| 137         | -183            | 12/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 70     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 138         | -183            | 12/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 70     |
| 139         | -183            | 12/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 71     |
| 140         | -171            | 01/04/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 72     |
| 141         | -157            | 01/18/2012                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr              | 30          | 30  | Tablet                       | PDTS   | 73     |
| 142         | -152            | 01/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 74     |
| 143         | -152            | 01/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 74     |
| 144         | -152            | 01/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 75     |
| 145         | -144            | 01/31/2012                     |                | Rx        | 00054001725 |     |                    |       |                                           | Prednisone                  | 90          | 90  | Tablet                       | PDTS   | 76     |
| 146         | -127            | 02/17/2012                     |                | Dx        | 7881        |     | Intmed             | 1     | Dysuria                                   |                             |             |     |                              | TEDN   | 77     |
| 147         | -127            | 02/17/2012                     |                | Dx        | 78097       |     | Intmed             | 2     | Altered Mental Status                     |                             |             |     |                              | TEDN   | 77     |
| 148         | -127            | 02/17/2012                     |                | Px        | 81002       |     | Intmed             | 1     | Urnl Dip Stick/Tablet Rgnt Non-Auto W/O   |                             |             |     |                              | TEDN   | 77     |
| 149         | -127            | 02/17/2012                     |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 78     |
| 150         | -121            | 02/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 79     |
| 151         | -121            | 02/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 79     |
| 152         | -121            | 02/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 80     |
| 153         | -110            | 03/05/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 81     |
| 154         | -92             | 03/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 82     |
| 155         | -92             | 03/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 82     |
| 156         | -92             | 03/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 83     |
| 157         | -83             | 04/01/2012                     |                | Rx        | 00054001729 |     |                    |       |                                           | Prednisone                  | 90          | 90  | Tablet                       | PDTS   | 84     |
| 158         | -81             | 04/03/2012                     |                | Dx        | 37515       |     | Oph                | 1     | Uns Tear Film Insufficiency               |                             |             |     |                              | TEDN   | 85     |
| 159         | -81             | 04/03/2012                     |                | Dx        | 36501       |     | Oph                | 2     | Op Angle Borderline Low Risk              |                             |             |     |                              | TEDN   | 85     |
| 160         | -81             | 04/03/2012                     |                | Dx        | 36257       |     | Oph                | 3     | Drusen (Degenerative) Of Retina           |                             |             |     |                              | TEDN   | 85     |
| 161         | -81             | 04/03/2012                     |                | Px        | 76514       |     | Oph                | 1     | Ophthalmic Us Dx Corneal Pachymetry Uni/B |                             |             |     |                              | TEDN   | 85     |
| 162         | -81             | 04/03/2012                     |                | Px        | 92014       |     | Oph                | 1     | Ophth Medical Xm&eval Comprhnsv Estab Pt  |                             |             |     |                              | TEDN   | 86     |
| 163         | -81             | 04/03/2012                     |                | Px        | 92250       |     | Oph                | 1     | Fundus Photography W/Interpretation & Rep |                             |             |     |                              | TEDN   | 87     |
| 164         | -73             | 04/11/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 88     |
| 165         | -61             | 04/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 90     |
| 166         | -61             | 04/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 90     |
| 167         | -61             | 04/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 91     |
| 168         | -61             | 04/23/2012                     |                | Rx        | 68180075103 |     |                    |       |                                           | Amlodipine Besylate         | 90          | 90  | Tablet                       | PDTS   | 89     |
| 169         | -57             | 04/27/2012                     |                | Dx        | 7102        |     | Intmed             | 1     | Sicca Syndrome                            |                             |             |     |                              | TEDN   | 92     |
| 170         | -57             | 04/27/2012                     |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 92     |
| 171         | -53             | 05/01/2012                     |                | Rx        | 65862001705 |     |                    |       |                                           | Amoxicillin                 | 7           | 30  | Capsule (Hard, Soft, Etc.)   | PDTS   | 93     |
| 172         | -31             | 05/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 94     |
| 173         | -31             | 05/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 94     |
| 174         | -31             | 05/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 95     |
| 175         | -28             | 05/26/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 96     |
| 176         | -19             | 06/04/2012                     |                | Dx        | 38021       |     | Intmed             | 1     | Cholesteatoma External Ear                |                             |             |     |                              | TEDN   | 98     |
| 177         | -19             | 06/04/2012                     |                | Dx        | 7804        |     | Intmed             | 2     | Dizziness And Giddiness                   |                             |             |     |                              | TEDN   | 98     |
| 178         | -19             | 06/04/2012                     |                | Dx        | 38870       |     | Intmed             | 3     | Otagia Unspecified                        |                             |             |     |                              | TEDN   | 98     |
| 179         | -19             | 06/04/2012                     |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 98     |
| 180         | -19             | 06/04/2012                     |                | Rx        | 24208063110 |     |                    |       |                                           | Neomycin-Polymyxin-Hydrocor | 16          | 10  | Solution, Non-Oral           | PDTS   | 97     |
| 181         | -18             | 06/05/2012                     |                | Dx        | 42731       |     | Gp                 | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 99     |
| 182         | -18             | 06/05/2012                     |                | Dx        | 7840        |     | Gp                 | 2     | Headache                                  |                             |             |     |                              | TEDN   | 99     |
| 183         | -18             | 06/05/2012                     |                | Dx        | 78079       |     | Gp                 | 3     | Other Malaise And Fatigue                 |                             |             |     |                              | TEDN   | 99     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 184         | -18             | 06/05/2012                     |                | Dx        | 4019  |      | Gp                 | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 99     |
| 185         | -18             | 06/05/2012                     |                | Px        | 93010 |      | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 99     |
| 186         | -18             | 06/05/2012                     |                | Px        | 99285 |      | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 100    |
| 187         | -18             | 06/05/2012                     |                | Dx        | 7840  |      | Radio              | 1     | Headache                                  |                        |             |     |                  | TEDN   | 101    |
| 188         | -18             | 06/05/2012                     |                | Px        | 70450 |      | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 101    |
| 189         | -17             | 06/06/2012                     |                | Dx        | 43330 |      | Gensurg            | 1     | Occlus Mult Bilat Precer Art Wo Inf       |                        |             |     |                  | TEDN   | 104    |
| 190         | -17             | 06/06/2012                     |                | Px        | 93880 |      | Gensurg            | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                        |             |     |                  | TEDN   | 104    |
| 191         | -17             | 06/06/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 102    |
| 192         | -17             | 06/06/2012                     |                | Dx        | 4011  | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 102    |
| 193         | -17             | 06/06/2012                     |                | Dx        | 2720  | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                        |             |     |                  | TEDN   | 102    |
| 194         | -17             | 06/06/2012                     |                | Dx        | 5789  | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 102    |
| 195         | -17             | 06/06/2012                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 102    |
| 196         | -17             | 06/06/2012                     |                | Px        | 99223 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 103    |
| 197         | -17             | 06/06/2012                     |                | Dx        | 43491 | Inpt | Cardvasc           | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 105    |
| 198         | -17             | 06/06/2012                     |                | Dx        | 42732 | Inpt | Cardvasc           | 2     | Atrial Flutter                            |                        |             |     |                  | TEDN   | 105    |
| 199         | -17             | 06/06/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 105    |
| 200         | -17             | 06/06/2012                     |                | Dx        | 72989 | Inpt | Cardvasc           | 4     | Oth Musculoskeletal Sympt Limbs           |                        |             |     |                  | TEDN   | 105    |
| 201         | -17             | 06/06/2012                     |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 105    |
| 202         | -17             | 06/06/2012                     |                | Dx        | 4359  | Inpt | Intmed             | 1     | Uns Transient Cerebral Ischemia           |                        |             |     |                  | TEDN   | 106    |
| 203         | -17             | 06/06/2012                     |                | Dx        | 42732 | Inpt | Intmed             | 2     | Atrial Flutter                            |                        |             |     |                  | TEDN   | 106    |
| 204         | -17             | 06/06/2012                     |                | Px        | 99223 | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 106    |
| 205         | -17             | 06/06/2012                     |                | Dx        | 7220  | Inpt | Radio              | 1     | Displaced Cervical Intervert Disc         |                        |             |     |                  | TEDN   | 107    |
| 206         | -17             | 06/06/2012                     |                | Dx        | 7224  | Inpt | Radio              | 2     | Degeneration Cervical Iv Disc             |                        |             |     |                  | TEDN   | 107    |
| 207         | -17             | 06/06/2012                     |                | Px        | 72141 | Inpt | Radio              | 1     | Mri Spinal Canal Cervical W/O Contrast Ma |                        |             |     |                  | TEDN   | 107    |
| 208         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 108    |
| 209         | -16             | 06/07/2012                     |                | Px        | 93312 | Inpt | Cardvasc           | 1     | Ecg Transesophag R-T 2d W/Prb Img Acquisj |                        |             |     |                  | TEDN   | 108    |
| 210         | -16             | 06/07/2012                     |                | Px        | 93320 | Inpt | Cardvasc           | 1     | Doppler Echocard Pulse Wave W/Spectral Di |                        |             |     |                  | TEDN   | 109    |
| 211         | -16             | 06/07/2012                     |                | Px        | 93325 | Inpt | Cardvasc           | 1     | Dop Echocard Color Flow Velocity Mapping  |                        |             |     |                  | TEDN   | 110    |
| 212         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 111    |
| 213         | -16             | 06/07/2012                     |                | Dx        | 4011  | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 111    |
| 214         | -16             | 06/07/2012                     |                | Dx        | 2720  | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                        |             |     |                  | TEDN   | 111    |
| 215         | -16             | 06/07/2012                     |                | Dx        | 5789  | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 111    |
| 216         | -16             | 06/07/2012                     |                | Px        | 92960 | Inpt | Cardvasc           | 1     | Cardioversion Elective Arrhythmia Externa |                        |             |     |                  | TEDN   | 111    |
| 217         | -16             | 06/07/2012                     |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 112    |
| 218         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 113    |
| 219         | -16             | 06/07/2012                     |                | Dx        | 436   | Inpt | Intmed             | 2     | Acute Ill Defined Cv Disease              |                        |             |     |                  | TEDN   | 113    |
| 220         | -16             | 06/07/2012                     |                | Dx        | V5861 | Inpt | Intmed             | 3     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 113    |
| 221         | -16             | 06/07/2012                     |                | Px        | 99232 | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 113    |
| 222         | -16             | 06/07/2012                     |                | Dx        | 43491 | Inpt | Radio              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 114    |
| 223         | -16             | 06/07/2012                     |                | Px        | 70553 | Inpt | Radio              | 1     | Mri Brain Brain Stem W/O &w/Contrast Mate |                        |             |     |                  | TEDN   | 114    |
| 224         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 118    |
| 225         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43820 |      |                    | 2     | Hemiplegia Uns Side Cv Disease            |                        |             |     |                  | TEDI   | 118    |
| 226         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43882 |      |                    | 3     | Dysphagia Cerebrovascular Disease         |                        |             |     |                  | TEDI   | 118    |
| 227         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43889 |      |                    | 4     | Oth Late Effects Cv Disease               |                        |             |     |                  | TEDI   | 118    |
| 228         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7812  |      |                    | 5     | Abnormality Of Gait                       |                        |             |     |                  | TEDI   | 118    |
| 229         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 42731 |      |                    | 6     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 118    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|------|--------------------|-------|-------------------------------------------|-------------------------|-------------|-----|------------------|--------|--------|
| 230         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 29420            |      |                    | 7     | Dementia Unspec Wo Behav Disturb          |                         |             |     |                  | TEDI   | 118    |
| 231         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7202             |      |                    | 8     | Sacroiliitis Other                        |                         |             |     |                  | TEDI   | 118    |
| 232         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7102             |      |                    | 9     | Sicca Syndrome                            |                         |             |     |                  | TEDI   | 118    |
| 233         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | V5861            |      |                    | 10    | Encounter Long Term Anticoagulant         |                         |             |     |                  | TEDI   | 118    |
| 234         | -15             | 06/08/2012                     |                | Dx        | 42731            | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 115    |
| 235         | -15             | 06/08/2012                     |                | Dx        | 4011             | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                         |             |     |                  | TEDN   | 115    |
| 236         | -15             | 06/08/2012                     |                | Dx        | 2720             | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                         |             |     |                  | TEDN   | 115    |
| 237         | -15             | 06/08/2012                     |                | Dx        | 5789             | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                         |             |     |                  | TEDN   | 115    |
| 238         | -15             | 06/08/2012                     |                | Px        | 99231            | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                         |             |     |                  | TEDN   | 115    |
| 239         | -15             | 06/08/2012                     |                | Dx        | 42731            | Inpt | Intmed             | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 116    |
| 240         | -15             | 06/08/2012                     |                | Dx        | 436              | Inpt | Intmed             | 2     | Acute Ill Defined Cv Disease              |                         |             |     |                  | TEDN   | 116    |
| 241         | -15             | 06/08/2012                     |                | Dx        | V5861            | Inpt | Intmed             | 3     | Encounter Long Term Anticoagulant         |                         |             |     |                  | TEDN   | 116    |
| 242         | -15             | 06/08/2012                     |                | Px        | 99238            | Inpt | Intmed             | 1     | Hospital Discharge Day Management 30 Min/ |                         |             |     |                  | TEDN   | 116    |
| 243         | -15             | 06/08/2012                     |                | Dx        | 725              | Inpt | Grpprac            | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 117    |
| 244         | -15             | 06/08/2012                     |                | Dx        | 7102             | Inpt | Grpprac            | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 117    |
| 245         | -15             | 06/08/2012                     |                | Px        | 99222            | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                         |             |     |                  | TEDN   | 117    |
| 246         | -12             | 06/11/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 119    |
| 247         | -12             | 06/11/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 119    |
| 248         | -12             | 06/11/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 119    |
| 249         | -11             | 06/12/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 120    |
| 250         | -11             | 06/12/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 120    |
| 251         | -11             | 06/12/2012                     |                | Px        | 99231            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 15 Minutes         |                         |             |     |                  | TEDN   | 120    |
| 252         | -10             | 06/13/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 121    |
| 253         | -10             | 06/13/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 121    |
| 254         | -10             | 06/13/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 121    |
| 255         | -8              | 06/15/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 122    |
| 256         | -8              | 06/15/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 122    |
| 257         | -8              | 06/15/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 122    |
| 258         | -1              | 06/22/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 123    |
| 259         | -1              | 06/22/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 123    |
| 260         | -1              | 06/22/2012                     |                | Px        | 99238            | Inpt | Physi              | 1     | Hospital Discharge Day Management 30 Min/ |                         |             |     |                  | TEDN   | 123    |
| 261         | 0               | 06/23/2012                     |                | Dx        | 79902            |      | Medic              | 1     | Hypoxemia                                 |                         |             |     |                  | TEDN   | 127    |
| 262         | 0               | 06/23/2012                     |                | Px        | E0431            |      | Medic              | 1     | Portable Gaseous O2                       |                         |             |     |                  | TEDN   | 127    |
| 263         | 0               | 06/23/2012                     |                | Px        | E1390            |      | Medic              | 1     | Oxygen Concentrator                       |                         |             |     |                  | TEDN   | 128    |
| 264         | 0               | 06/23/2012                     |                | Rx        | 00406051201      |      |                    |       |                                           | Oxycodone-Acetaminophen | 5           | 30  | Tablet           | PDTS   | 124    |
| 265         | 0               | 06/23/2012                     |                | Rx        | 51672402703      |      |                    |       |                                           | Warfarin Sodium         | 30          | 30  | Tablet           | PDTS   | 125    |
| 266         | 0               | 06/23/2012                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG        | 30          |     | INITIAL FILL     | PDTS   | 126    |
| 267         | 2               | 06/25/2012                     |                | Dx        | 42731            |      | Intmed             | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 129    |
| 268         | 2               | 06/25/2012                     |                | Px        | 85610            |      | Intmed             | 1     | Prothrombin Time                          |                         |             |     |                  | TEDN   | 129    |
| 269         | 2               | 06/25/2012                     |                | Px        | 99213            |      | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                         |             |     |                  | TEDN   | 130    |
| 270         | 4               | 06/27/2012                     |                | Dx        | 42731            |      | Cardvasc           | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 133    |
| 271         | 4               | 06/27/2012                     |                | Dx        | 4011             |      | Cardvasc           | 2     | Benign Essential Hypertension             |                         |             |     |                  | TEDN   | 133    |
| 272         | 4               | 06/27/2012                     |                | Dx        | 4242             |      | Cardvasc           | 3     | Tricuspid Valve Disorders Nonrheum        |                         |             |     |                  | TEDN   | 133    |
| 273         | 4               | 06/27/2012                     |                | Dx        | 4240             |      | Cardvasc           | 4     | Mitral Valve Disorders                    |                         |             |     |                  | TEDN   | 133    |
| 274         | 4               | 06/27/2012                     |                | Px        | 99215            |      | Cardvasc           | 1     | Office Outpatient Visit 40 Minutes        |                         |             |     |                  | TEDN   | 133    |



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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code             | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description      | Days Supply | QTY | Drug Formulation             | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 275         | 4               | 06/27/2012                     |                | Rx        | 68180051403      |     |                    |       |                                           | Lisinopril                  | 30          | 30  | Tablet                       | PDTS   | 131    |
| 276         | 4               | 06/27/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide         | 30          | 30  | Tablet                       | PDTS   | 132    |
| 277         | 6               | 06/29/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 134    |
| 278         | 6               | 06/29/2012                     |                | Px        | 92960            |     | Cardvasc           | 1     | Cardioversion Elective Arrhythmia Externa |                             |             |     |                              | TEDN   | 134    |
| 279         | 9               | 07/02/2012                     |                | Dx        | 7102             |     | Intmed             | 1     | Sicca Syndrome                            |                             |             |     |                              | TEDN   | 135    |
| 280         | 9               | 07/02/2012                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 135    |
| 281         | 9               | 07/02/2012                     |                | Dx        | 7812             |     | Intmed             | 3     | Abnormality Of Gait                       |                             |             |     |                              | TEDN   | 135    |
| 282         | 9               | 07/02/2012                     |                | Px        | G0180            |     | Intmed             | 1     | Md Certification Hha Patient              |                             |             |     |                              | TEDN   | 135    |
| 283         | 10              | 07/03/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 136    |
| 284         | 10              | 07/03/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 136    |
| 285         | 10              | 07/03/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 137    |
| 286         | 16              | 07/09/2012                     |                | Rx        | 53746027205      |     |                    |       |                                           | Sulfamethoxazole-Trimethopr | 7           | 14  | Tablet                       | PDTS   | 138    |
| 287         | 17              | 07/10/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 140    |
| 288         | 17              | 07/10/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 140    |
| 289         | 17              | 07/10/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 141    |
| 290         | 17              | 07/10/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 139    |
| 291         | 20              | 07/13/2012                     |                | Dx        | 7245             |     | Facility           | 1     | Backache Unspecified                      |                             |             |     |                              | TEDN   | 144    |
| 292         | 20              | 07/13/2012                     |                | Px        | 72110            |     | Facility           | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                             |             |     |                              | TEDN   | 144    |
| 293         | 20              | 07/13/2012                     |                | Dx        | 7213             |     | Radio              | 1     | Lumbosacral Spondylosis                   |                             |             |     |                              | TEDN   | 143    |
| 294         | 20              | 07/13/2012                     |                | Px        | 72110            |     | Radio              | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                             |             |     |                              | TEDN   | 143    |
| 295         | 20              | 07/13/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       | INDEX STUDY DRUG                          |                             | 30          |     | REFILL                       | PDTS   | 142    |
| 296         | 24              | 07/17/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 146    |
| 297         | 24              | 07/17/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 146    |
| 298         | 24              | 07/17/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 147    |
| 299         | 24              | 07/17/2012                     |                | Rx        | 51672402703      |     |                    |       |                                           | Warfarin Sodium             | 90          | 180 | Tablet                       | PDTS   | 145    |
| 300         | 27              | 07/20/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide         | 30          | 30  | Tablet                       | PDTS   | 148    |
| 301         | 30              | 07/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 149    |
| 302         | 30              | 07/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 149    |
| 303         | 30              | 07/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 150    |
| 304         | 31              | 07/24/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 151    |
| 305         | 31              | 07/24/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 151    |
| 306         | 31              | 07/24/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 152    |
| 307         | 34              | 07/27/2012                     |                | Dx        | 7241             |     | Intmed             | 1     | Pain In Thoracic Spine                    |                             |             |     |                              | TEDN   | 155    |
| 308         | 34              | 07/27/2012                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 155    |
| 309         | 34              | 07/27/2012                     |                | Dx        | 7881             |     | Intmed             | 3     | Dysuria                                   |                             |             |     |                              | TEDN   | 155    |
| 310         | 34              | 07/27/2012                     |                | Px        | 81002            |     | Intmed             | 1     | Urnl Dip Stick/Tablet Rgnt Non-Auto W/O   |                             |             |     |                              | TEDN   | 155    |
| 311         | 34              | 07/27/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 156    |
| 312         | 34              | 07/27/2012                     |                | Rx        | 63481068706      |     |                    |       |                                           | Lidoderm                    | 30          | 30  | Adhesive Patch, Medicated    | PDTS   | 153    |
| 313         | 34              | 07/27/2012                     |                | Rx        | 00406051201      |     |                    |       |                                           | Oxycodone-Acetaminophen     | 33          | 50  | Tablet                       | PDTS   | 154    |
| 314         | 38              | 07/31/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 157    |
| 315         | 38              | 07/31/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 157    |
| 316         | 38              | 07/31/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 158    |
| 317         | 38              | 07/31/2012                     |                | Dx        | 72142            |     | Facility           | 1     | Spondylosis W Myelopathy Lumbar           |                             |             |     |                              | TEDN   | 159    |
| 318         | 38              | 07/31/2012                     |                | Dx        | 73730            |     | Facility           | 2     | Scoliosis Idiopathic                      |                             |             |     |                              | TEDN   | 159    |
| 319         | 38              | 07/31/2012                     |                | Dx        | 72402            |     | Facility           | 3     | Spinal Stenos Lumbar Wo Neur Claud        |                             |             |     |                              | TEDN   | 159    |
| 320         | 38              | 07/31/2012                     |                | Px        | 72158            |     | Facility           | 1     | Mri Spinal Canal Lumbar W/O &w/Contr Matr |                             |             |     |                              | TEDN   | 159    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 321         | 38              | 07/31/2012                     |                | Dx        | 8054             |     | Radio              | 1     | Fracture Lumbar Vertebra Close            |                        |             |     |                              | TEDN   | 160    |
| 322         | 38              | 07/31/2012                     |                | Dx        | E887             |     | Radio              | 2     | Fracture In Accidental Fall Uns           |                        |             |     |                              | TEDN   | 160    |
| 323         | 38              | 07/31/2012                     |                | Px        | 72158            |     | Radio              | 1     | Mri Spinal Canal Lumbar W/O &w/Contr Matr |                        |             |     |                              | TEDN   | 160    |
| 324         | 45              | 08/07/2012                     |                | Dx        | 37515            |     | Opth               | 1     | Uns Tear Film Insufficiency               |                        |             |     |                              | TEDN   | 161    |
| 325         | 45              | 08/07/2012                     |                | Dx        | 36501            |     | Opth               | 2     | Op Angle Borderline Low Risk              |                        |             |     |                              | TEDN   | 161    |
| 326         | 45              | 08/07/2012                     |                | Dx        | 36257            |     | Opth               | 3     | Drusen (Degenerative) Of Retina           |                        |             |     |                              | TEDN   | 161    |
| 327         | 45              | 08/07/2012                     |                | Px        | 92012            |     | Opth               | 1     | Opth Medical Xm&eval Intermediate Estab   |                        |             |     |                              | TEDN   | 161    |
| 328         | 45              | 08/07/2012                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 162    |
| 329         | 45              | 08/07/2012                     |                | Dx        | 2449             |     | Grppract           | 2     | Uns Hypothyroidism                        |                        |             |     |                              | TEDN   | 162    |
| 330         | 45              | 08/07/2012                     |                | Dx        | 538              |     | Grppract           | 3     | Gastrointestinal Mucositis                |                        |             |     |                              | TEDN   | 162    |
| 331         | 45              | 08/07/2012                     |                | Dx        | 4240             |     | Grppract           | 4     | Mitral Valve Disorders                    |                        |             |     |                              | TEDN   | 162    |
| 332         | 45              | 08/07/2012                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 162    |
| 333         | 49              | 08/11/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide    | 90          | 90  | Tablet                       | PDTS   | 163    |
| 334         | 49              | 08/11/2012                     |                | Rx        | 68180051403      |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                       | PDTS   | 164    |
| 335         | 49              | 08/11/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 165    |
| 336         | 49              | 08/11/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 166    |
| 337         | 51              | 08/13/2012                     |                | Rx        | 00054001725      |     |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 167    |
| 338         | 52              | 08/14/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 168    |
| 339         | 52              | 08/14/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 168    |
| 340         | 52              | 08/14/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 169    |
| 341         | 61              | 08/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 170    |
| 342         | 61              | 08/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 170    |
| 343         | 61              | 08/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 171    |
| 344         | 62              | 08/24/2012                     |                | Dx        | 73313            |     | Intmed             | 1     | Pathological Fracture Vertebrae           |                        |             |     |                              | TEDN   | 172    |
| 345         | 62              | 08/24/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 172    |
| 346         | 69              | 08/31/2012                     |                | Dx        | 42731            |     | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 173    |
| 347         | 69              | 08/31/2012                     |                | Dx        | 7242             |     | Intmed             | 2     | Lumbago                                   |                        |             |     |                              | TEDN   | 173    |
| 348         | 69              | 08/31/2012                     |                | Px        | G0179            |     | Intmed             | 1     | Md Recertification Hha Pt                 |                        |             |     |                              | TEDN   | 173    |
| 349         | 69              | 08/31/2012                     |                | Dx        | 8054             |     | Radio              | 1     | Fracture Lumbar Vertebra Close            |                        |             |     |                              | TEDN   | 174    |
| 350         | 69              | 08/31/2012                     |                | Px        | 22521            |     | Radio              | 1     | Percutaneous Vertebroplasty Lumbar W/Wo B |                        |             |     |                              | TEDN   | 174    |
| 351         | 69              | 08/31/2012                     |                | Px        | 72291            |     | Radio              | 1     | Rad S&i Perq Vrtpls/Sacrplsty Pr Vrt Body |                        |             |     |                              | TEDN   | 175    |
| 352         | 69              | 08/31/2012                     |                | Px        | 85027            |     | Grppract           | 1     | Blood Count Complete Automated            |                        |             |     |                              | TEDN   | 176    |
| 353         | 69              | 08/31/2012                     |                | Px        | 85610            |     | Grppract           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 177    |
| 354         | 69              | 08/31/2012                     |                | Px        | 85730            |     | Grppract           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                              | TEDN   | 178    |
| 355         | 73              | 09/04/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 179    |
| 356         | 73              | 09/04/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 179    |
| 357         | 73              | 09/04/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 180    |
| 358         | 77              | 09/08/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 181    |
| 359         | 79              | 09/10/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 182    |
| 360         | 87              | 09/18/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 183    |
| 361         | 87              | 09/18/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 183    |
| 362         | 87              | 09/18/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 184    |
| 363         | 92              | 09/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 185    |
| 364         | 92              | 09/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 185    |
| 365         | 92              | 09/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 186    |
| 366         | 93              | 09/24/2012                     |                | Dx        | 7213             |     | Radio              | 1     | Lumbosacral Spondylosis                   |                        |             |     |                              | TEDN   | 188    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 367         | 93              | 09/24/2012                     |                | Px        | 72110            |     | Radio              | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                        |             |     |                               | TEDN   | 188    |
| 368         | 93              | 09/24/2012                     |                | Dx        | 7241             |     | Intmed             | 1     | Pain In Thoracic Spine                    |                        |             |     |                               | TEDN   | 189    |
| 369         | 93              | 09/24/2012                     |                | Dx        | 73313            |     | Intmed             | 2     | Pathological Fracture Vertebrae           |                        |             |     |                               | TEDN   | 189    |
| 370         | 93              | 09/24/2012                     |                | Dx        | V0481            |     | Intmed             | 3     | Vaccine For Influenza                     |                        |             |     |                               | TEDN   | 189    |
| 371         | 93              | 09/24/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 189    |
| 372         | 93              | 09/24/2012                     |                | Px        | G0008            |     | Intmed             | 1     | Admin Influenza Virus Vac                 |                        |             |     |                               | TEDN   | 190    |
| 373         | 93              | 09/24/2012                     |                | Px        | Q2037            |     | Intmed             | 1     | Fluvirin Vacc, 3 Yrs & >, Im              |                        |             |     |                               | TEDN   | 191    |
| 374         | 93              | 09/24/2012                     |                | Dx        | 73300            |     | Facility           | 1     | Osteoporosis Unspec                       |                        |             |     |                               | TEDN   | 192    |
| 375         | 93              | 09/24/2012                     |                | Dx        | 7212             |     | Facility           | 2     | Thoracic Spondylosis Wo Myelopathy        |                        |             |     |                               | TEDN   | 192    |
| 376         | 93              | 09/24/2012                     |                | Dx        | 7213             |     | Facility           | 3     | Lumbosacral Spondylosis                   |                        |             |     |                               | TEDN   | 192    |
| 377         | 93              | 09/24/2012                     |                | Dx        | V4589            |     | Facility           | 4     | Oth Postsurgical Status                   |                        |             |     |                               | TEDN   | 192    |
| 378         | 93              | 09/24/2012                     |                | Px        | 72110            |     | Facility           | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                        |             |     |                               | TEDN   | 192    |
| 379         | 93              | 09/24/2012                     |                | Rx        | 00603307932      |     |                    |       |                                           | Cyclobenzaprine Hcl    | 15          | 15  | Tablet                        | PDTS   | 187    |
| 380         | 101             | 10/02/2012                     |                | Dx        | 42731            |     | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 194    |
| 381         | 101             | 10/02/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 194    |
| 382         | 101             | 10/02/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 195    |
| 383         | 101             | 10/02/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 193    |
| 384         | 109             | 10/10/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 196    |
| 385         | 115             | 10/16/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 197    |
| 386         | 115             | 10/16/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 197    |
| 387         | 115             | 10/16/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 198    |
| 388         | 122             | 10/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 199    |
| 389         | 122             | 10/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 199    |
| 390         | 122             | 10/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 200    |
| 391         | 131             | 11/01/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 201    |
| 392         | 131             | 11/01/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 201    |
| 393         | 131             | 11/01/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 202    |
| 394         | 134             | 11/04/2012                     |                | Rx        | 51672402703      |     |                    |       |                                           | Warfarin Sodium        | 90          | 180 | Tablet                        | PDTS   | 203    |
| 395         | 134             | 11/04/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 204    |
| 396         | 135             | 11/05/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                        | PDTS   | 205    |
| 397         | 141             | 11/11/2012                     |                | Rx        | 00054001729      |     |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                        | PDTS   | 206    |
| 398         | 141             | 11/11/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 207    |
| 399         | 143             | 11/13/2012                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 209    |
| 400         | 143             | 11/13/2012                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension             |                        |             |     |                               | TEDN   | 209    |
| 401         | 143             | 11/13/2012                     |                | Px        | 93040            |     | Grppract           | 1     | Rhythm Ecg 1-3 Leads W/Interpretation & R |                        |             |     |                               | TEDN   | 209    |
| 402         | 143             | 11/13/2012                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 210    |
| 403         | 143             | 11/13/2012                     |                | Rx        | 63304062410      |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 208    |
| 404         | 145             | 11/15/2012                     |                | Rx        | 00245005815      |     |                    |       |                                           | Klor-Con M20           | 12          | 38  | Tablet, SR,particles/Crystals | PDTS   | 211    |
| 405         | 153             | 11/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 212    |
| 406         | 153             | 11/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 212    |
| 407         | 153             | 11/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 213    |
| 408         | 157             | 11/27/2012                     |                | Dx        | 4280             |     | Intmed             | 1     | Congestive Heart Failure Unspec           |                        |             |     |                               | TEDN   | 214    |
| 409         | 157             | 11/27/2012                     |                | Dx        | 45111            |     | Intmed             | 2     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 214    |
| 410         | 157             | 11/27/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 214    |
| 411         | 157             | 11/27/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 215    |
| 412         | 172             | 12/12/2012                     |                | Rx        | 63304062410      |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 216    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 413         | 172             | 12/12/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 217    |
| 414         | 172             | 12/12/2012                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 12          | 38  | Tablet, SR,particles/Crystals | PDTS   | 218    |
| 415         | 178             | 12/18/2012                     |                | Dx        | 4280        |     | Intmed             | 1     | Congestive Heart Failure Unspec           |                        |             |     |                               | TEDN   | 220    |
| 416         | 178             | 12/18/2012                     |                | Dx        | 42731       |     | Intmed             | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 220    |
| 417         | 178             | 12/18/2012                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 220    |
| 418         | 178             | 12/18/2012                     |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 221    |
| 419         | 178             | 12/18/2012                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 219    |
| 420         | 183             | 12/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 222    |
| 421         | 183             | 12/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 222    |
| 422         | 183             | 12/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 223    |
| 423         | 198             | 01/07/2013                     |                | Dx        | 7847        |     | Gp                 | 1     | Epistaxis                                 |                        |             |     |                               | TEDN   | 224    |
| 424         | 198             | 01/07/2013                     |                | Dx        | 59970       |     | Gp                 | 2     | Hematuria Unspecified                     |                        |             |     |                               | TEDN   | 224    |
| 425         | 198             | 01/07/2013                     |                | Dx        | 42731       |     | Gp                 | 3     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 224    |
| 426         | 198             | 01/07/2013                     |                | Dx        | 4019        |     | Gp                 | 4     | Unspecified Essential Hypertension        |                        |             |     |                               | TEDN   | 224    |
| 427         | 198             | 01/07/2013                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                               | TEDN   | 224    |
| 428         | 198             | 01/07/2013                     |                | Dx        | 7847        |     | Facility           | 1     | Epistaxis                                 |                        |             |     |                               | TEDN   | 225    |
| 429         | 198             | 01/07/2013                     |                | Dx        | 59971       |     | Facility           | 2     | Gross Hematuria                           |                        |             |     |                               | TEDN   | 225    |
| 430         | 198             | 01/07/2013                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                               | TEDN   | 225    |
| 431         | 198             | 01/07/2013                     |                | Px        | 81001       |     | Facility           | 1     | Urns Dip Stick/Tablet Reagent Auto Micro  |                        |             |     |                               | TEDN   | 226    |
| 432         | 198             | 01/07/2013                     |                | Px        | 85027       |     | Facility           | 1     | Blood Count Complete Automated            |                        |             |     |                               | TEDN   | 227    |
| 433         | 198             | 01/07/2013                     |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 228    |
| 434         | 198             | 01/07/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                               | TEDN   | 229    |
| 435         | 201             | 01/10/2013                     |                | Dx        | 7030        |     | Podia              | 1     | Ingrowing Nail                            |                        |             |     |                               | TEDN   | 230    |
| 436         | 201             | 01/10/2013                     |                | Dx        | 7038        |     | Podia              | 2     | Other Diseases Nail                       |                        |             |     |                               | TEDN   | 230    |
| 437         | 201             | 01/10/2013                     |                | Dx        | 700         |     | Podia              | 3     | Corns/Callosities                         |                        |             |     |                               | TEDN   | 230    |
| 438         | 201             | 01/10/2013                     |                | Dx        | 44020       |     | Podia              | 4     | Uns Atherosclerosis Extremities           |                        |             |     |                               | TEDN   | 230    |
| 439         | 201             | 01/10/2013                     |                | Px        | 11055       |     | Podia              | 1     | Paring/Cutting Benign Hyperkeratotic Lesi |                        |             |     |                               | TEDN   | 230    |
| 440         | 201             | 01/10/2013                     |                | Px        | 11721       |     | Podia              | 1     | Debridement Nail Any Method 6/>           |                        |             |     |                               | TEDN   | 231    |
| 441         | 201             | 01/10/2013                     |                | Px        | 11730       |     | Podia              | 1     | Avulsion Nail Plate Partial/Complete Simp |                        |             |     |                               | TEDN   | 232    |
| 442         | 201             | 01/10/2013                     |                | Px        | 99203       |     | Podia              | 1     | Office Outpatient New 30 Minutes          |                        |             |     |                               | TEDN   | 233    |
| 443         | 206             | 01/15/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 235    |
| 444         | 206             | 01/15/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 235    |
| 445         | 206             | 01/15/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 236    |
| 446         | 206             | 01/15/2013                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 234    |
| 447         | 207             | 01/16/2013                     |                | Rx        | 63304062410 |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 237    |
| 448         | 209             | 01/18/2013                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 238    |
| 449         | 213             | 01/22/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 239    |
| 450         | 213             | 01/22/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 239    |
| 451         | 213             | 01/22/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 240    |
| 452         | 214             | 01/23/2013                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 241    |
| 453         | 214             | 01/23/2013                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 241    |
| 454         | 214             | 01/23/2013                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 242    |
| 455         | 215             | 01/24/2013                     |                | Rx        | 68180051403 |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 243    |
| 456         | 215             | 01/24/2013                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 38          | 38  | Tablet, SR,particles/Crystals | PDTS   | 244    |
| 457         | 220             | 01/29/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 245    |
| 458         | 220             | 01/29/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 245    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 459         | 220             | 01/29/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 246    |
| 460         | 227             | 02/05/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 247    |
| 461         | 227             | 02/05/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 247    |
| 462         | 227             | 02/05/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 248    |
| 463         | 232             | 02/10/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 249    |
| 464         | 232             | 02/10/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG       | 90          |     | REFILL                        | PDTS   | 250    |
| 465         | 232             | 02/10/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 251    |
| 466         | 233             | 02/11/2013                     |                | Rx        | 00054001729      |     |                    |       |                                      | Prednisone             | 90          | 90  | Tablet                        | PDTS   | 252    |
| 467         | 241             | 02/19/2013                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                  |                        |             |     |                               | TEDN   | 254    |
| 468         | 241             | 02/19/2013                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension        |                        |             |     |                               | TEDN   | 254    |
| 469         | 241             | 02/19/2013                     |                | Dx        | 4240             |     | Grppract           | 3     | Mitral Valve Disorders               |                        |             |     |                               | TEDN   | 254    |
| 470         | 241             | 02/19/2013                     |                | Dx        | 4242             |     | Grppract           | 4     | Tricuspid Valve Disorders Nonrheum   |                        |             |     |                               | TEDN   | 254    |
| 471         | 241             | 02/19/2013                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes   |                        |             |     |                               | TEDN   | 254    |
| 472         | 241             | 02/19/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 255    |
| 473         | 241             | 02/19/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 255    |
| 474         | 241             | 02/19/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 256    |
| 475         | 241             | 02/19/2013                     |                | Rx        | 62037099905      |     |                    |       |                                      | Potassium Chloride     | 90          | 90  | Tablet, SR,particles/Crystals | PDTS   | 253    |
| 476         | 245             | 02/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 257    |
| 477         | 245             | 02/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 257    |
| 478         | 245             | 02/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                        |             |     |                               | TEDN   | 258    |
| 479         | 248             | 02/26/2013                     |                | Rx        | 68645028254      |     |                    |       |                                      | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 259    |
| 480         | 253             | 03/03/2013                     |                | Rx        | 51672402703      |     |                    |       |                                      | Warfarin Sodium        | 90          | 180 | Tablet                        | PDTS   | 260    |
| 481         | 258             | 03/08/2013                     |                | Rx        | 53489021510      |     |                    |       |                                      | Clonidine Hcl          | 30          | 30  | Tablet                        | PDTS   | 261    |
| 482         | 262             | 03/12/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 262    |
| 483         | 262             | 03/12/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 262    |
| 484         | 262             | 03/12/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 263    |
| 485         | 266             | 03/16/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 264    |
| 486         | 266             | 03/16/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 265    |
| 487         | 269             | 03/19/2013                     |                | Dx        | 4280             |     | Intmed             | 1     | Congestive Heart Failure Unspec      |                        |             |     |                               | TEDN   | 266    |
| 488         | 269             | 03/19/2013                     |                | Dx        | 4011             |     | Intmed             | 2     | Benign Essential Hypertension        |                        |             |     |                               | TEDN   | 266    |
| 489         | 269             | 03/19/2013                     |                | Px        | 99214            |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes   |                        |             |     |                               | TEDN   | 266    |
| 490         | 273             | 03/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 267    |
| 491         | 273             | 03/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 267    |
| 492         | 273             | 03/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                        |             |     |                               | TEDN   | 268    |
| 493         | 281             | 03/31/2013                     |                | Rx        | 68645028254      |     |                    |       |                                      | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 269    |
| 494         | 281             | 03/31/2013                     |                | Rx        | 53489021510      |     |                    |       |                                      | Clonidine Hcl          | 30          | 30  | Tablet                        | PDTS   | 270    |
| 495         | 284             | 04/03/2013                     |                | Rx        | 68180051403      |     |                    |       |                                      | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 271    |
| 496         | 290             | 04/09/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 272    |
| 497         | 290             | 04/09/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 273    |
| 498         | 293             | 04/12/2013                     |                | Dx        | 6826             |     | Intmed             | 1     | Cellulitis/Abscess Leg Ex Foot       |                        |             |     |                               | TEDN   | 275    |
| 499         | 293             | 04/12/2013                     |                | Dx        | 45111            |     | Intmed             | 2     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 275    |
| 500         | 293             | 04/12/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 275    |
| 501         | 293             | 04/12/2013                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes   |                        |             |     |                               | TEDN   | 276    |
| 502         | 293             | 04/12/2013                     |                | Rx        | 68180012202      |     |                    |       |                                      | Cephalexin             | 7           | 21  | Capsule (Hard, Soft, Etc.)    | PDTS   | 274    |
| 503         | 304             | 04/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 277    |
| 504         | 304             | 04/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 277    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 505         | 304             | 04/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                                | TEDN   | 278    |
| 506         | 312             | 05/01/2013                     |                | Rx        | 00054001729      |     |                    |       |                                            | Prednisone             | 90          | 90  | Tablet                         | PDTS   | 279    |
| 507         | 312             | 05/01/2013                     |                | Rx        | 53489021510      |     |                    |       |                                            | Clonidine Hcl          | 30          | 30  | Tablet                         | PDTS   | 280    |
| 508         | 312             | 05/01/2013                     |                | Rx        | 68645028254      |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                         | PDTS   | 281    |
| 509         | 318             | 05/07/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                                | TEDN   | 282    |
| 510         | 318             | 05/07/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                                | TEDN   | 282    |
| 511         | 318             | 05/07/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 282    |
| 512         | 318             | 05/07/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                                | TEDN   | 283    |
| 513         | 323             | 05/12/2013                     |                | Rx        | 63304062410      |     |                    |       |                                            | Furosemide             | 30          | 30  | Tablet                         | PDTS   | 284    |
| 514         | 323             | 05/12/2013                     |                | Rx        | 55111015810      |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)   | PDTS   | 285    |
| 515         | 323             | 05/12/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                            | INDEX STUDY DRUG       | 90          |     | REFILL                         | PDTS   | 286    |
| 516         | 334             | 05/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                                | TEDN   | 287    |
| 517         | 334             | 05/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                                | TEDN   | 287    |
| 518         | 334             | 05/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                                | TEDN   | 288    |
| 519         | 346             | 06/04/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                                | TEDN   | 291    |
| 520         | 346             | 06/04/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                                | TEDN   | 291    |
| 521         | 346             | 06/04/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 291    |
| 522         | 346             | 06/04/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                                | TEDN   | 292    |
| 523         | 346             | 06/04/2013                     |                | Rx        | 68645028254      |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                         | PDTS   | 289    |
| 524         | 346             | 06/04/2013                     |                | Rx        | 53489021510      |     |                    |       |                                            | Clonidine Hcl          | 30          | 30  | Tablet                         | PDTS   | 290    |
| 525         | 348             | 06/06/2013                     |                | Rx        | 00245005815      |     |                    |       |                                            | Klor-Con M20           | 90          | 90  | Tablet, SR, particles/Crystals | PDTS   | 293    |
| 526         | 352             | 06/10/2013                     |                | Rx        | 68180051403      |     |                    |       |                                            | Lisinopril             | 30          | 60  | Tablet                         | PDTS   | 294    |
| 527         | 353             | 06/11/2013                     |                | Rx        | 55111015810      |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)   | PDTS   | 295    |
| 528         | 353             | 06/11/2013                     |                | Rx        | 63304062410      |     |                    |       |                                            | Furosemide             | 30          | 30  | Tablet                         | PDTS   | 296    |
| 529         | 356             | 06/14/2013                     |                | Dx        | 78903            |     | Gp                 | 1     | Abdom Pain R Lower Quad                    |                        |             |     |                                | TEDN   | 298    |
| 530         | 356             | 06/14/2013                     |                | Dx        | 56400            |     | Gp                 | 2     | Unspec Constipation                        |                        |             |     |                                | TEDN   | 298    |
| 531         | 356             | 06/14/2013                     |                | Dx        | 5990             |     | Gp                 | 3     | Urinary Tract Infection Unspec             |                        |             |     |                                | TEDN   | 298    |
| 532         | 356             | 06/14/2013                     |                | Dx        | 56032            |     | Gp                 | 4     | Fecal Impaction                            |                        |             |     |                                | TEDN   | 298    |
| 533         | 356             | 06/14/2013                     |                | Px        | 99285            |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                                | TEDN   | 298    |
| 534         | 356             | 06/14/2013                     |                | Dx        | 78909            |     | Facility           | 1     | Abdominal Pain Other Site                  |                        |             |     |                                | TEDN   | 299    |
| 535         | 356             | 06/14/2013                     |                | Dx        | 56400            |     | Facility           | 2     | Unspec Constipation                        |                        |             |     |                                | TEDN   | 299    |
| 536         | 356             | 06/14/2013                     |                | Dx        | 56032            |     | Facility           | 3     | Fecal Impaction                            |                        |             |     |                                | TEDN   | 299    |
| 537         | 356             | 06/14/2013                     |                | Dx        | 5990             |     | Facility           | 4     | Urinary Tract Infection Unspec             |                        |             |     |                                | TEDN   | 299    |
| 538         | 356             | 06/14/2013                     |                | Dx        | 55320            |     | Facility           | 5     | Ventral Hernia Unspec                      |                        |             |     |                                | TEDN   | 299    |
| 539         | 356             | 06/14/2013                     |                | Dx        | 5533             |     | Facility           | 6     | Diaphragmatic Hernia                       |                        |             |     |                                | TEDN   | 299    |
| 540         | 356             | 06/14/2013                     |                | Dx        | 4019             |     | Facility           | 7     | Unspecified Essential Hypertension         |                        |             |     |                                | TEDN   | 299    |
| 541         | 356             | 06/14/2013                     |                | Dx        | 2449             |     | Facility           | 8     | Uns Hypothyroidism                         |                        |             |     |                                | TEDN   | 299    |
| 542         | 356             | 06/14/2013                     |                | Px        | 74177            |     | Facility           | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                                | TEDN   | 299    |
| 543         | 356             | 06/14/2013                     |                | Px        | 80053            |     | Facility           | 1     | Comprehensive Metabolic Panel              |                        |             |     |                                | TEDN   | 300    |
| 544         | 356             | 06/14/2013                     |                | Px        | 81001            |     | Facility           | 1     | Urnl's Dip Stick/Tablet Reagent Auto Micro |                        |             |     |                                | TEDN   | 301    |
| 545         | 356             | 06/14/2013                     |                | Px        | 83605            |     | Facility           | 1     | Lactate                                    |                        |             |     |                                | TEDN   | 302    |
| 546         | 356             | 06/14/2013                     |                | Px        | 85025            |     | Facility           | 1     | Blood Count Complete Auto&auto Difrn'l Wb  |                        |             |     |                                | TEDN   | 303    |
| 547         | 356             | 06/14/2013                     |                | Px        | 85610            |     | Facility           | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 304    |
| 548         | 356             | 06/14/2013                     |                | Px        | 85730            |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole   |                        |             |     |                                | TEDN   | 305    |
| 549         | 356             | 06/14/2013                     |                | Px        | 87077            |     | Facility           | 1     | Cul Bact Aerobic Add'l Meths Definitive Ea |                        |             |     |                                | TEDN   | 306    |
| 550         | 356             | 06/14/2013                     |                | Px        | 87086            |     | Facility           | 1     | Culture Bacterial Quanttative Colony Coun  |                        |             |     |                                | TEDN   | 307    |

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| 551         | 356             | 06/14/2013                     |                | Px        | 87186       |     | Facility           | 1     | Susceptibly Stdy Antimicrobial Micro/Agar |                             |             |     |                              | TEDN   | 308    |
| 552         | 356             | 06/14/2013                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                             |             |     |                              | TEDN   | 309    |
| 553         | 356             | 06/14/2013                     |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                             |             |     |                              | TEDN   | 310    |
| 554         | 356             | 06/14/2013                     |                | Dx        | 78909       |     | Radio              | 1     | Abdominal Pain Other Site                 |                             |             |     |                              | TEDN   | 311    |
| 555         | 356             | 06/14/2013                     |                | Dx        | 56400       |     | Radio              | 2     | Unspec Constipation                       |                             |             |     |                              | TEDN   | 311    |
| 556         | 356             | 06/14/2013                     |                | Dx        | 6259        |     | Radio              | 3     | Uns Symptom Female Genital Organs         |                             |             |     |                              | TEDN   | 311    |
| 557         | 356             | 06/14/2013                     |                | Px        | 74177       |     | Radio              | 1     | Ct Abdoen & Pelvis W/Contrast Material    |                             |             |     |                              | TEDN   | 311    |
| 558         | 356             | 06/14/2013                     |                | Rx        | 43598022114 |     |                    |       |                                           | Amox Tr-Potassium Clavulana | 10          | 20  | Tablet                       | PDTS   | 297    |
| 559         | 360             | 06/18/2013                     |                | Dx        | 42731       |     | Grppract           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 312    |
| 560         | 360             | 06/18/2013                     |                | Dx        | 4011        |     | Grppract           | 2     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 312    |
| 561         | 360             | 06/18/2013                     |                | Dx        | 2449        |     | Grppract           | 3     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 312    |
| 562         | 360             | 06/18/2013                     |                | Px        | 93040       |     | Grppract           | 1     | Rhythm Ecg 1-3 Leads W/Interpretation & R |                             |             |     |                              | TEDN   | 312    |
| 563         | 360             | 06/18/2013                     |                | Px        | 99213       |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 313    |
| 564         | 378             | 07/06/2013                     |                | Rx        | 51672402703 |     |                    |       |                                           | Warfarin Sodium             | 90          | 180 | Tablet                       | PDTS   | 314    |
| 565         | 378             | 07/06/2013                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr              | 30          | 30  | Tablet                       | PDTS   | 315    |
| 566         | 388             | 07/16/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 320    |
| 567         | 388             | 07/16/2013                     |                | Dx        | 42731       |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 320    |
| 568         | 388             | 07/16/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 320    |
| 569         | 388             | 07/16/2013                     |                | Rx        | 63304062410 |     |                    |       |                                           | Furosemide                  | 90          | 90  | Tablet                       | PDTS   | 316    |
| 570         | 388             | 07/16/2013                     |                | Rx        | 00591040810 |     |                    |       |                                           | Lisinopril                  | 90          | 90  | Tablet                       | PDTS   | 317    |
| 571         | 388             | 07/16/2013                     |                | Rx        | 53489021510 |     |                    |       |                                           | Clonidine Hcl               | 90          | 90  | Tablet                       | PDTS   | 318    |
| 572         | 388             | 07/16/2013                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 319    |
| 573         | 389             | 07/17/2013                     |                | Dx        | 9596        |     | Ambul              | 1     | Oth/Uns Injury Hip/Thigh                  |                             |             |     |                              | TEDN   | 328    |
| 574         | 389             | 07/17/2013                     |                | Px        | A0425       |     | Ambul              | 1     | Ground Mileage                            |                             |             |     |                              | TEDN   | 328    |
| 575         | 389             | 07/17/2013                     |                | Px        | A0427       |     | Ambul              | 1     | Als1-Emergency                            |                             |             |     |                              | TEDN   | 329    |
| 576         | 389             | 07/17/2013                     |                | Dx        | 82009       |     | Gp                 | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDN   | 321    |
| 577         | 389             | 07/17/2013                     |                | Dx        | 7197        |     | Gp                 | 2     | Difficulty In Walking                     |                             |             |     |                              | TEDN   | 321    |
| 578         | 389             | 07/17/2013                     |                | Dx        | 4019        |     | Gp                 | 3     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 321    |
| 579         | 389             | 07/17/2013                     |                | Dx        | E8888       |     | Gp                 | 4     | Other Fall                                |                             |             |     |                              | TEDN   | 321    |
| 580         | 389             | 07/17/2013                     |                | Px        | 99285       |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                             |             |     |                              | TEDN   | 321    |
| 581         | 389             | 07/17/2013                     |                | Dx        | 82009       |     | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDN   | 322    |
| 582         | 389             | 07/17/2013                     |                | Dx        | E8889       |     | Radio              | 2     | Unspecified Fall                          |                             |             |     |                              | TEDN   | 322    |
| 583         | 389             | 07/17/2013                     |                | Dx        | 71945       |     | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                             |             |     |                              | TEDN   | 322    |
| 584         | 389             | 07/17/2013                     |                | Px        | 72170       |     | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                             |             |     |                              | TEDN   | 322    |
| 585         | 389             | 07/17/2013                     |                | Px        | 73510       |     | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                             |             |     |                              | TEDN   | 323    |
| 586         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 82009       |     |                    | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDI   | 330    |
| 587         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 51881       |     |                    | 2     | Respiratory Failure                       |                             |             |     |                              | TEDI   | 330    |
| 588         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 78550       |     |                    | 3     | Shock Unspecified                         |                             |             |     |                              | TEDI   | 330    |
| 589         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 570         |     |                    | 4     | Acute/Subacute Necrosis Liver             |                             |             |     |                              | TEDI   | 330    |
| 590         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 45381       |     |                    | 5     | Ac Emb/Throm Superficial Upper Ext        |                             |             |     |                              | TEDI   | 330    |
| 591         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 41401       |     |                    | 6     | Atheroscler Native Coronary Art           |                             |             |     |                              | TEDI   | 330    |
| 592         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 42731       |     |                    | 7     | Atrial Fibrillation                       |                             |             |     |                              | TEDI   | 330    |
| 593         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 5939        |     |                    | 8     | Uns Disorder Kidney/Ureter                |                             |             |     |                              | TEDI   | 330    |
| 594         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 2875        |     |                    | 9     | Uns Thrombocytopenia                      |                             |             |     |                              | TEDI   | 330    |
| 595         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 725         |     |                    | 10    | Polymyalgia Rheumatica                    |                             |             |     |                              | TEDI   | 330    |
| 596         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 7102        |     |                    | 11    | Sicca Syndrome                            |                             |             |     |                              | TEDI   | 330    |



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| 597         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 78079 |      |                    | 12    | Other Malaise And Fatigue                 |                        |             |     |                  | TEDI   | 330    |
| 598         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 7935  |      |                    | 1     | Open Reduction Int Fix Femur              |                        |             |     |                  | TEDI   | 330    |
| 599         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 3897  |      |                    | 2     | Central Line Placement W Guidance         |                        |             |     |                  | TEDI   | 330    |
| 600         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 0017  |      |                    | 3     | Infusion Of Vasopressor Agent             |                        |             |     |                  | TEDI   | 330    |
| 601         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 9907  |      |                    | 4     | Transfusion Of Other Serum                |                        |             |     |                  | TEDI   | 330    |
| 602         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 9904  |      |                    | 5     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 330    |
| 603         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 5794  |      |                    | 6     | Insertion Indwelling Cath                 |                        |             |     |                  | TEDI   | 330    |
| 604         | 389             | 07/17/2013                     |                | Dx        | 82009 | Inpt | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                  | TEDN   | 324    |
| 605         | 389             | 07/17/2013                     |                | Dx        | V4589 | Inpt | Radio              | 2     | Oth Postsurgical Status                   |                        |             |     |                  | TEDN   | 324    |
| 606         | 389             | 07/17/2013                     |                | Px        | 73500 | Inpt | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 324    |
| 607         | 389             | 07/17/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 325    |
| 608         | 389             | 07/17/2013                     |                | Px        | 01220 | Inpt | Anesth             | 1     | Anesthesia Closed Procedures Upper 2/3 Fe |                        |             |     |                  | TEDN   | 325    |
| 609         | 389             | 07/17/2013                     |                | Dx        | 82100 | Inpt | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 326    |
| 610         | 389             | 07/17/2013                     |                | Px        | 27236 | Inpt | Ortho              | 1     | Optx Fem Fx Prox End Nck Int Fixj/Prostc  |                        |             |     |                  | TEDN   | 326    |
| 611         | 389             | 07/17/2013                     |                | Px        | 99223 | Inpt | Ortho              | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 327    |
| 612         | 390             | 07/18/2013                     |                | Dx        | 82009 | Inpt | Grppract           | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                  | TEDN   | 331    |
| 613         | 390             | 07/18/2013                     |                | Dx        | 51881 | Inpt | Grppract           | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 331    |
| 614         | 390             | 07/18/2013                     |                | Dx        | 78550 | Inpt | Grppract           | 3     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 331    |
| 615         | 390             | 07/18/2013                     |                | Dx        | 570   | Inpt | Grppract           | 4     | Acute/Subacute Necrosis Liver             |                        |             |     |                  | TEDN   | 331    |
| 616         | 390             | 07/18/2013                     |                | Px        | 93010 | Inpt | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 331    |
| 617         | 391             | 07/19/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 1     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 332    |
| 618         | 391             | 07/19/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 332    |
| 619         | 391             | 07/19/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 3     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 332    |
| 620         | 391             | 07/19/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 332    |
| 621         | 392             | 07/20/2013                     |                | Dx        | 5180  | Inpt | Radio              | 1     | Pulmonary Collapse                        |                        |             |     |                  | TEDN   | 333    |
| 622         | 392             | 07/20/2013                     |                | Dx        | 5119  | Inpt | Radio              | 2     | Unspecif Pleural Effusion                 |                        |             |     |                  | TEDN   | 333    |
| 623         | 392             | 07/20/2013                     |                | Px        | 71275 | Inpt | Radio              | 1     | Ct Angiography Chest W/Contrast/Noncontra |                        |             |     |                  | TEDN   | 333    |
| 624         | 392             | 07/20/2013                     |                | Dx        | 78550 | Inpt | Pulmo              | 1     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 334    |
| 625         | 392             | 07/20/2013                     |                | Dx        | 51881 | Inpt | Pulmo              | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 334    |
| 626         | 392             | 07/20/2013                     |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 334    |
| 627         | 392             | 07/20/2013                     |                | Px        | 99292 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 335    |
| 628         | 392             | 07/20/2013                     |                | Dx        | 78609 | Inpt | Radio              | 1     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 336    |
| 629         | 392             | 07/20/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 336    |
| 630         | 392             | 07/20/2013                     |                | Dx        | V5881 | Inpt | Radio              | 1     | Fitting/Adjust Vascular Catheter          |                        |             |     |                  | TEDN   | 337    |
| 631         | 392             | 07/20/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 337    |
| 632         | 393             | 07/21/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 338    |
| 633         | 393             | 07/21/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 338    |
| 634         | 393             | 07/21/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 338    |
| 635         | 393             | 07/21/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 338    |
| 636         | 393             | 07/21/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 338    |
| 637         | 393             | 07/21/2013                     |                | Dx        | 78609 | Inpt | Radio              | 1     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 339    |
| 638         | 393             | 07/21/2013                     |                | Dx        | 7869  | Inpt | Radio              | 2     | Other Respiratory Symptoms                |                        |             |     |                  | TEDN   | 339    |
| 639         | 393             | 07/21/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 339    |
| 640         | 393             | 07/21/2013                     |                | Dx        | 7906  | Inpt | Radio              | 1     | Oth Abnormal Blood Chemistry              |                        |             |     |                  | TEDN   | 340    |
| 641         | 393             | 07/21/2013                     |                | Dx        | 78550 | Inpt | Radio              | 2     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 340    |



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| 642         | 393             | 07/21/2013                     |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 340    |
| 643         | 393             | 07/21/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 341    |
| 644         | 393             | 07/21/2013                     |                | Px        | 36556 | Inpt | Anesth             | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 341    |
| 645         | 393             | 07/21/2013                     |                | Px        | 76937 | Inpt | Anesth             | 1     | Us Vasc Access Sits Vsl Patency Ndl Entry |                        |             |     |                  | TEDN   | 342    |
| 646         | 394             | 07/22/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 343    |
| 647         | 394             | 07/22/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 343    |
| 648         | 394             | 07/22/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 343    |
| 649         | 394             | 07/22/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 343    |
| 650         | 394             | 07/22/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 343    |
| 651         | 394             | 07/22/2013                     |                | Dx        | 514   | Inpt | Radio              | 1     | Pulmonary Congestion/Hypostasis           |                        |             |     |                  | TEDN   | 344    |
| 652         | 394             | 07/22/2013                     |                | Dx        | 78609 | Inpt | Radio              | 2     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 344    |
| 653         | 394             | 07/22/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 344    |
| 654         | 394             | 07/22/2013                     |                | Dx        | 78550 | Inpt | Pulmo              | 1     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 345    |
| 655         | 394             | 07/22/2013                     |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 345    |
| 656         | 394             | 07/22/2013                     |                | Dx        | 9597  | Inpt | Radio              | 1     | Oth/Uns Injury Knee Leg Ankle/Foot        |                        |             |     |                  | TEDN   | 346    |
| 657         | 394             | 07/22/2013                     |                | Dx        | 71906 | Inpt | Radio              | 2     | Effusion Of Joint Lower Leg               |                        |             |     |                  | TEDN   | 346    |
| 658         | 394             | 07/22/2013                     |                | Dx        | E8889 | Inpt | Radio              | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 346    |
| 659         | 394             | 07/22/2013                     |                | Px        | 73564 | Inpt | Radio              | 1     | Radiologic Exam Knee Complete 4/More View |                        |             |     |                  | TEDN   | 346    |
| 660         | 395             | 07/23/2013                     |                | Dx        | 79902 |      | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 350    |
| 661         | 395             | 07/23/2013                     |                | Px        | E0431 |      | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 350    |
| 662         | 395             | 07/23/2013                     |                | Px        | E1390 |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 351    |
| 663         | 395             | 07/23/2013                     |                | Dx        | 4371  | Inpt | Radio              | 1     | Oth Generalized Ischemic Cv Disease       |                        |             |     |                  | TEDN   | 347    |
| 664         | 395             | 07/23/2013                     |                | Dx        | 3319  | Inpt | Radio              | 2     | Uns Cerebral Degeneration                 |                        |             |     |                  | TEDN   | 347    |
| 665         | 395             | 07/23/2013                     |                | Px        | 70450 | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 347    |
| 666         | 395             | 07/23/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 348    |
| 667         | 395             | 07/23/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 348    |
| 668         | 395             | 07/23/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 348    |
| 669         | 395             | 07/23/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 348    |
| 670         | 395             | 07/23/2013                     |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 348    |
| 671         | 395             | 07/23/2013                     |                | Dx        | 5849  | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 349    |
| 672         | 395             | 07/23/2013                     |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 349    |
| 673         | 395             | 07/23/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 352    |
| 674         | 395             | 07/23/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 2     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 352    |
| 675         | 395             | 07/23/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 352    |
| 676         | 395             | 07/23/2013                     |                | Dx        | 4011  | Inpt | Grppract           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 352    |
| 677         | 395             | 07/23/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 352    |
| 678         | 396             | 07/24/2013                     |                | Dx        | 486   | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 353    |
| 679         | 396             | 07/24/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 353    |
| 680         | 396             | 07/24/2013                     |                | Dx        | 5849  | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 354    |
| 681         | 396             | 07/24/2013                     |                | Px        | 99232 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 354    |
| 682         | 396             | 07/24/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 355    |
| 683         | 396             | 07/24/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 2     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 355    |
| 684         | 396             | 07/24/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 355    |
| 685         | 396             | 07/24/2013                     |                | Dx        | 4011  | Inpt | Grppract           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 355    |
| 686         | 396             | 07/24/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 355    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 687         | 397             | 07/25/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 356    |
| 688         | 397             | 07/25/2013                     |                | Dx        | 4589        | Inpt | Grpract            | 2     | Hypotension Unspecified                   |                        |             |     |                            | TEDN   | 356    |
| 689         | 397             | 07/25/2013                     |                | Dx        | 42731       | Inpt | Grpract            | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 356    |
| 690         | 397             | 07/25/2013                     |                | Dx        | 4011        | Inpt | Grpract            | 4     | Benign Essential Hypertension             |                        |             |     |                            | TEDN   | 356    |
| 691         | 397             | 07/25/2013                     |                | Px        | 99232       | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                            | TEDN   | 356    |
| 692         | 398             | 07/26/2013                     |                | Dx        | 5849        | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                            | TEDN   | 360    |
| 693         | 398             | 07/26/2013                     |                | Px        | 99231       | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                            | TEDN   | 360    |
| 694         | 398             | 07/26/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 361    |
| 695         | 398             | 07/26/2013                     |                | Dx        | 4589        | Inpt | Grpract            | 2     | Hypotension Unspecified                   |                        |             |     |                            | TEDN   | 361    |
| 696         | 398             | 07/26/2013                     |                | Dx        | 42731       | Inpt | Grpract            | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 361    |
| 697         | 398             | 07/26/2013                     |                | Dx        | 4011        | Inpt | Grpract            | 4     | Benign Essential Hypertension             |                        |             |     |                            | TEDN   | 361    |
| 698         | 398             | 07/26/2013                     |                | Px        | 99238       | Inpt | Grpract            | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                            | TEDN   | 361    |
| 699         | 398             | 07/26/2013                     |                | Dx        | 4928        |      | Ambul              | 1     | Other Emphysema                           |                        |             |     |                            | TEDN   | 358    |
| 700         | 398             | 07/26/2013                     |                | Dx        | 8208        |      | Ambul              | 2     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 358    |
| 701         | 398             | 07/26/2013                     |                | Dx        | 71945       |      | Ambul              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                            | TEDN   | 358    |
| 702         | 398             | 07/26/2013                     |                | Dx        | 9072        |      | Ambul              | 4     | Late Effect Of Spinal Cord Inj            |                        |             |     |                            | TEDN   | 358    |
| 703         | 398             | 07/26/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                            | TEDN   | 358    |
| 704         | 398             | 07/26/2013                     |                | Px        | A0428       |      | Ambul              | 1     | Bls                                       |                        |             |     |                            | TEDN   | 359    |
| 705         | 398             | 07/26/2013                     |                | Rx        | 49884086702 |      |                    |       |                                           | Dronabinol             | 7           | 40  | Capsule (Hard, Soft, Etc.) | PDTS   | 357    |
| 706         | 401             | 07/29/2013                     |                | Dx        | 8208        |      | Intmed             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 362    |
| 707         | 401             | 07/29/2013                     |                | Dx        | 78559       |      | Intmed             | 2     | Other Shock Without Trauma                |                        |             |     |                            | TEDN   | 362    |
| 708         | 401             | 07/29/2013                     |                | Dx        | 78820       |      | Intmed             | 3     | Retention Of Urine Unspecified            |                        |             |     |                            | TEDN   | 362    |
| 709         | 401             | 07/29/2013                     |                | Px        | 99306       |      | Intmed             | 1     | Initial Nursing Facility Care/Day High Se |                        |             |     |                            | TEDN   | 362    |
| 710         | 403             | 07/31/2013                     |                | Dx        | 8208        |      | Pa                 | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 363    |
| 711         | 403             | 07/31/2013                     |                | Dx        | 33829       |      | Pa                 | 2     | Other Chronic Pain                        |                        |             |     |                            | TEDN   | 363    |
| 712         | 403             | 07/31/2013                     |                | Dx        | 2801        |      | Pa                 | 3     | Iron Def Anemia Inadeq Iron Intake        |                        |             |     |                            | TEDN   | 363    |
| 713         | 403             | 07/31/2013                     |                | Px        | 99310       |      | Pa                 | 1     | Sbsq Nurs Facil Care/Day Unstabl/New Prob |                        |             |     |                            | TEDN   | 363    |
| 714         | 403             | 07/31/2013                     |                | Dx        | 99649       |      | Misce              | 1     | Ot Malfun Int Orthped Device/Grf          |                        |             |     |                            | TEDN   | 364    |
| 715         | 403             | 07/31/2013                     |                | Dx        | 82009       |      | Misce              | 2     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                            | TEDN   | 364    |
| 716         | 403             | 07/31/2013                     |                | Dx        | V5409       |      | Misce              | 3     | Other Aftercare Internal Fix Device       |                        |             |     |                            | TEDN   | 364    |
| 717         | 403             | 07/31/2013                     |                | Px        | 73510       |      | Misce              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                            | TEDN   | 364    |
| 718         | 404             | 08/01/2013                     |                | Dx        | 7813        |      | Ambul              | 1     | Lack Of Coordination                      |                        |             |     |                            | TEDN   | 365    |
| 719         | 404             | 08/01/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                            | TEDN   | 365    |
| 720         | 404             | 08/01/2013                     |                | Px        | A0427       |      | Ambul              | 1     | Als1-Emergency                            |                        |             |     |                            | TEDN   | 366    |
| 721         | 404             | 08/01/2013                     |                | Dx        | 8208        |      | Intmed             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 370    |
| 722         | 404             | 08/01/2013                     |                | Dx        | 78559       |      | Intmed             | 2     | Other Shock Without Trauma                |                        |             |     |                            | TEDN   | 370    |
| 723         | 404             | 08/01/2013                     |                | Dx        | 78820       |      | Intmed             | 3     | Retention Of Urine Unspecified            |                        |             |     |                            | TEDN   | 370    |
| 724         | 404             | 08/01/2013                     |                | Px        | 99308       |      | Intmed             | 1     | Sbsq Nursing Facil Care/Day Minor Complj  |                        |             |     |                            | TEDN   | 370    |
| 725         | 404             | 08/01/2013                     |                | Px        | 99356       |      | Intmed             | 1     | Prolonged Service I/P Req Unit/Floor Time |                        |             |     |                            | TEDN   | 371    |
| 726         | 404             | 08/01/2013                     |                | Dx        | 82009       | Inpt | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                            | TEDN   | 367    |
| 727         | 404             | 08/01/2013                     |                | Dx        | E9289       | Inpt | Radio              | 2     | Uns Accident                              |                        |             |     |                            | TEDN   | 367    |
| 728         | 404             | 08/01/2013                     |                | Dx        | V7282       | Inpt | Radio              | 3     | Preop Respiratory Examination             |                        |             |     |                            | TEDN   | 367    |
| 729         | 404             | 08/01/2013                     |                | Dx        | 4293        | Inpt | Radio              | 4     | Cardiomegaly                              |                        |             |     |                            | TEDN   | 367    |
| 730         | 404             | 08/01/2013                     |                | Px        | 71010       | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                            | TEDN   | 367    |
| 731         | 404             | 08/01/2013                     |                | Px        | 73510       | Inpt | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                            | TEDN   | 368    |
| 732         | 404             | 08/01/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 369    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 733         | 404             | 08/01/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 369    |
| 734         | 404             | 08/01/2013                     |                | Px        | 99222 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 369    |
| 735         | 405             | 08/02/2013                     |                | Dx        | 71595 | Inpt | Radio              | 1     | Osteoarthritis Unsp Pelvis/Thigh          |                        |             |     |                  | TEDN   | 372    |
| 736         | 405             | 08/02/2013                     |                | Dx        | 71945 | Inpt | Radio              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 372    |
| 737         | 405             | 08/02/2013                     |                | Dx        | V4364 | Inpt | Radio              | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 372    |
| 738         | 405             | 08/02/2013                     |                | Dx        | V5481 | Inpt | Radio              | 4     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 372    |
| 739         | 405             | 08/02/2013                     |                | Px        | 72170 | Inpt | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 372    |
| 740         | 405             | 08/02/2013                     |                | Px        | 73500 | Inpt | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 373    |
| 741         | 405             | 08/02/2013                     |                | Dx        | 82021 | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 374    |
| 742         | 405             | 08/02/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 374    |
| 743         | 405             | 08/02/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 374    |
| 744         | 405             | 08/02/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 375    |
| 745         | 405             | 08/02/2013                     |                | Px        | 01230 | Inpt | Anesth             | 1     | Anesthesia Open Procedures Upper 2/3 Femu |                        |             |     |                  | TEDN   | 375    |
| 746         | 405             | 08/02/2013                     |                | Dx        | 82100 | Inpt | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 376    |
| 747         | 405             | 08/02/2013                     |                | Px        | 27125 | Inpt | Ortho              | 1     | Hemiarthroplasty Hip Partial              |                        |             |     |                  | TEDN   | 376    |
| 748         | 405             | 08/02/2013                     |                | Dx        | V7283 | Inpt | Grpract            | 1     | Other Pre Operative Examination           |                        |             |     |                  | TEDN   | 377    |
| 749         | 405             | 08/02/2013                     |                | Px        | 93010 | Inpt | Grpract            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 377    |
| 750         | 406             | 08/03/2013                     |                | Dx        | 82021 | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 378    |
| 751         | 406             | 08/03/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 378    |
| 752         | 406             | 08/03/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 378    |
| 753         | 408             | 08/05/2013                     |                | Dx        | 27541 | Inpt | Grpract            | 1     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 379    |
| 754         | 408             | 08/05/2013                     |                | Dx        | 2869  | Inpt | Grpract            | 2     | Oth/Uns Coagulation Defects               |                        |             |     |                  | TEDN   | 379    |
| 755         | 408             | 08/05/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 379    |
| 756         | 409             | 08/06/2013                     |                | Dx        | 27541 | Inpt | Grpract            | 1     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 380    |
| 757         | 409             | 08/06/2013                     |                | Dx        | 2869  | Inpt | Grpract            | 2     | Oth/Uns Coagulation Defects               |                        |             |     |                  | TEDN   | 380    |
| 758         | 409             | 08/06/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 380    |
| 759         | 409             | 08/06/2013                     |                | Dx        | 7813  |      | Ambul              | 1     | Lack Of Coordination                      |                        |             |     |                  | TEDN   | 381    |
| 760         | 409             | 08/06/2013                     |                | Px        | A0425 |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 381    |
| 761         | 409             | 08/06/2013                     |                | Px        | A0428 |      | Ambul              | 1     | Bls                                       |                        |             |     |                  | TEDN   | 382    |
| 762         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 383    |
| 763         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | V5409 |      |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 383    |
| 764         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 7197  |      |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 383    |
| 765         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 72887 |      |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 383    |
| 766         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 42731 |      |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 383    |
| 767         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 2875  |      |                    | 6     | Uns Thrombocytopenia                      |                        |             |     |                  | TEDI   | 383    |
| 768         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 41400 |      |                    | 7     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDI   | 383    |
| 769         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 7102  |      |                    | 8     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 383    |
| 770         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 725   |      |                    | 9     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 383    |
| 771         | 412             | 08/09/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 384    |
| 772         | 412             | 08/09/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 384    |
| 773         | 412             | 08/09/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 384    |
| 774         | 412             | 08/09/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 384    |
| 775         | 412             | 08/09/2013                     |                | Px        | 99305 |      | Gp                 | 1     | Initial Nursing Facility Care/Day Moder S |                        |             |     |                  | TEDN   | 384    |
| 776         | 415             | 08/12/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 385    |
| 777         | 415             | 08/12/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 385    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 778         | 415             | 08/12/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 385    |
| 779         | 415             | 08/12/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 385    |
| 780         | 415             | 08/12/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 385    |
| 781         | 418             | 08/15/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 386    |
| 782         | 418             | 08/15/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 386    |
| 783         | 418             | 08/15/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 386    |
| 784         | 418             | 08/15/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 386    |
| 785         | 418             | 08/15/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 386    |
| 786         | 418             | 08/15/2013                     |                | Dx        | 82100 |     | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 387    |
| 787         | 418             | 08/15/2013                     |                | Px        | 72170 |     | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 387    |
| 788         | 418             | 08/15/2013                     |                | Px        | 73500 |     | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 388    |
| 789         | 422             | 08/19/2013                     |                | Dx        | 2931  |     | Clinpsych          | 1     | Subacute Delirium                         |                        |             |     |                  | TEDN   | 389    |
| 790         | 422             | 08/19/2013                     |                | Dx        | 29020 |     | Clinpsych          | 2     | Senile Dementia W Delusional              |                        |             |     |                  | TEDN   | 389    |
| 791         | 422             | 08/19/2013                     |                | Px        | 90791 |     | Clinpsych          | 1     | 90791                                     |                        |             |     |                  | TEDN   | 389    |
| 792         | 422             | 08/19/2013                     |                | Px        | 96118 |     | Clinpsych          | 1     | Nuropsyc Testing Pr Hr W/Pt & Interpj Tim |                        |             |     |                  | TEDN   | 390    |
| 793         | 423             | 08/20/2013                     |                | Dx        | 78820 |     | Grpract            | 1     | Retention Of Urine Unspecified            |                        |             |     |                  | TEDN   | 391    |
| 794         | 423             | 08/20/2013                     |                | Px        | 51798 |     | Grpract            | 1     | Meas Post-Voiding Residual Urine&/Bldr Ca |                        |             |     |                  | TEDN   | 391    |
| 795         | 425             | 08/22/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 392    |
| 796         | 425             | 08/22/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 392    |
| 797         | 425             | 08/22/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 392    |
| 798         | 425             | 08/22/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 392    |
| 799         | 425             | 08/22/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 392    |
| 800         | 426             | 08/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 393    |
| 801         | 426             | 08/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 393    |
| 802         | 426             | 08/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 394    |
| 803         | 432             | 08/29/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 395    |
| 804         | 432             | 08/29/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 395    |
| 805         | 432             | 08/29/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 395    |
| 806         | 432             | 08/29/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 395    |
| 807         | 432             | 08/29/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 395    |
| 808         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | V5789 |     |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 396    |
| 809         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | V5409 |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 396    |
| 810         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 7197  |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 396    |
| 811         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 72887 |     |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 396    |
| 812         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 42731 |     |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 396    |
| 813         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 2875  |     |                    | 6     | Uns Thrombocytopenia                      |                        |             |     |                  | TEDI   | 396    |
| 814         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 41400 |     |                    | 7     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDI   | 396    |
| 815         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 7102  |     |                    | 8     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 396    |
| 816         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 725   |     |                    | 9     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 396    |
| 817         | 438             | 09/04/2013                     |                | Dx        | 5272  |     | Oto                | 1     | Sialoadenitis                             |                        |             |     |                  | TEDN   | 397    |
| 818         | 438             | 09/04/2013                     |                | Dx        | 4019  |     | Oto                | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 397    |
| 819         | 438             | 09/04/2013                     |                | Dx        | 42731 |     | Oto                | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 397    |
| 820         | 438             | 09/04/2013                     |                | Px        | 99203 |     | Oto                | 1     | Office Outpatient New 30 Minutes          |                        |             |     |                  | TEDN   | 397    |
| 821         | 438             | 09/04/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 398    |
| 822         | 438             | 09/04/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 398    |

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| 823         | 438             | 09/04/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 398    |
| 824         | 438             | 09/04/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 398    |
| 825         | 438             | 09/04/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 398    |
| 826         | 440             | 09/06/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 399    |
| 827         | 440             | 09/06/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 399    |
| 828         | 440             | 09/06/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 399    |
| 829         | 440             | 09/06/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 399    |
| 830         | 440             | 09/06/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 399    |
| 831         | 440             | 09/06/2013                     |                | Dx        | 82100 |      | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 400    |
| 832         | 440             | 09/06/2013                     |                | Px        | 72170 |      | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 400    |
| 833         | 440             | 09/06/2013                     |                | Px        | 73500 |      | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 401    |
| 834         | 442             | 09/08/2013                     |                | Dx        | 4928  |      | Ambul              | 1     | Other Emphysema                           |                        |             |     |                  | TEDN   | 403    |
| 835         | 442             | 09/08/2013                     |                | Dx        | 71945 |      | Ambul              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 403    |
| 836         | 442             | 09/08/2013                     |                | Dx        | 9072  |      | Ambul              | 3     | Late Effect Of Spinal Cord Inj            |                        |             |     |                  | TEDN   | 403    |
| 837         | 442             | 09/08/2013                     |                | Px        | A0425 |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 403    |
| 838         | 442             | 09/08/2013                     |                | Px        | A0427 |      | Ambul              | 1     | Als1-Emergency                            |                        |             |     |                  | TEDN   | 404    |
| 839         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Gp                 | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 405    |
| 840         | 442             | 09/08/2013                     |                | Dx        | 56211 |      | Gp                 | 2     | Diverticulitis Colon                      |                        |             |     |                  | TEDN   | 405    |
| 841         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Gp                 | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 405    |
| 842         | 442             | 09/08/2013                     |                | Px        | 99285 |      | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 405    |
| 843         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Radio              | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 406    |
| 844         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 2     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 406    |
| 845         | 442             | 09/08/2013                     |                | Px        | 72170 |      | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 406    |
| 846         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Radio              | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 407    |
| 847         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 2     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 407    |
| 848         | 442             | 09/08/2013                     |                | Dx        | 71945 |      | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 407    |
| 849         | 442             | 09/08/2013                     |                | Px        | 72192 |      | Radio              | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 407    |
| 850         | 442             | 09/08/2013                     |                | Px        | 73500 |      | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 408    |
| 851         | 442             | 09/08/2013                     |                | Dx        | 95909 |      | Radio              | 1     | Injury Face/Neck                          |                        |             |     |                  | TEDN   | 410    |
| 852         | 442             | 09/08/2013                     |                | Dx        | 7231  |      | Radio              | 2     | Cervicalgia                               |                        |             |     |                  | TEDN   | 410    |
| 853         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 410    |
| 854         | 442             | 09/08/2013                     |                | Dx        | 95901 |      | Radio              | 4     | Uns Head Injury                           |                        |             |     |                  | TEDN   | 410    |
| 855         | 442             | 09/08/2013                     |                | Px        | 70450 |      | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 410    |
| 856         | 442             | 09/08/2013                     |                | Px        | 72125 |      | Radio              | 1     | Ct Cervical Spine W/O Contrast Material   |                        |             |     |                  | TEDN   | 411    |
| 857         | 442             | 09/08/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 402    |
| 858         | 442             | 09/08/2013                     |                | Dx        | V5865 | Inpt | Grppract           | 2     | Long-Term Use Steroids                    |                        |             |     |                  | TEDN   | 402    |
| 859         | 442             | 09/08/2013                     |                | Dx        | V5861 | Inpt | Grppract           | 3     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 402    |
| 860         | 442             | 09/08/2013                     |                | Dx        | V4986 | Inpt | Grppract           | 4     | Do Not Resuscitate Status                 |                        |             |     |                  | TEDN   | 402    |
| 861         | 442             | 09/08/2013                     |                | Px        | 99223 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 402    |
| 862         | 442             | 09/08/2013                     |                | Dx        | 82100 | Inpt | Grppract           | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 409    |
| 863         | 442             | 09/08/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 409    |
| 864         | 443             | 09/09/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 412    |
| 865         | 443             | 09/09/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 412    |
| 866         | 443             | 09/09/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 412    |
| 867         | 443             | 09/09/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 413    |
| 868         | 443             | 09/09/2013                     |                | Px        | 01230 | Inpt | Anesth             | 1     | Anesthesia Open Procedures Upper 2/3 Femu |                        |             |     |                  | TEDN   | 413    |

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| 869         | 443             | 09/09/2013                     |                | Dx        | V5481 | Inpt | Radio              | 1     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 414    |
| 870         | 443             | 09/09/2013                     |                | Dx        | V4364 | Inpt | Radio              | 2     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 414    |
| 871         | 443             | 09/09/2013                     |                | Dx        | 71945 | Inpt | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 414    |
| 872         | 443             | 09/09/2013                     |                | Px        | 72170 | Inpt | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 414    |
| 873         | 443             | 09/09/2013                     |                | Px        | 73500 | Inpt | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 415    |
| 874         | 444             | 09/10/2013                     |                | Dx        | 82003 | Inpt | Ortho              | 1     | Fracture Base Femoral Nck Closed          |                        |             |     |                  | TEDN   | 416    |
| 875         | 444             | 09/10/2013                     |                | Px        | 27236 | Inpt | Ortho              | 1     | Optx Fem Fx Prox End Nck Int Fixj/Prostc  |                        |             |     |                  | TEDN   | 416    |
| 876         | 444             | 09/10/2013                     |                | Px        | 99222 | Inpt | Ortho              | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 417    |
| 877         | 444             | 09/10/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 418    |
| 878         | 444             | 09/10/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 418    |
| 879         | 444             | 09/10/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 418    |
| 880         | 445             | 09/11/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 419    |
| 881         | 445             | 09/11/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 419    |
| 882         | 445             | 09/11/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 419    |
| 883         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 420    |
| 884         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7197  |      |                    | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 420    |
| 885         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 72887 |      |                    | 3     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 420    |
| 886         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | V5409 |      |                    | 4     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 420    |
| 887         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7291  |      |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 420    |
| 888         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 725   |      |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 420    |
| 889         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7102  |      |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 420    |
| 890         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 33829 |      |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 420    |
| 891         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 73300 |      |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 420    |
| 892         | 446             | 09/12/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 421    |
| 893         | 446             | 09/12/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 421    |
| 894         | 446             | 09/12/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 421    |
| 895         | 446             | 09/12/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 421    |
| 896         | 446             | 09/12/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 421    |
| 897         | 450             | 09/16/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 422    |
| 898         | 450             | 09/16/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 422    |
| 899         | 450             | 09/16/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 422    |
| 900         | 450             | 09/16/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 422    |
| 901         | 450             | 09/16/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 422    |
| 902         | 453             | 09/19/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 423    |
| 903         | 453             | 09/19/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 423    |
| 904         | 453             | 09/19/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 423    |
| 905         | 453             | 09/19/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 423    |
| 906         | 453             | 09/19/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 423    |
| 907         | 457             | 09/23/2013                     |                | Dx        | 79902 |      | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 424    |
| 908         | 457             | 09/23/2013                     |                | Px        | E0431 |      | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 424    |
| 909         | 457             | 09/23/2013                     |                | Px        | E1390 |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 425    |
| 910         | 459             | 09/25/2013                     |                | Dx        | 71945 |      | Ortho              | 1     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 426    |
| 911         | 459             | 09/25/2013                     |                | Px        | 72170 |      | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 426    |
| 912         | 459             | 09/25/2013                     |                | Px        | 73500 |      | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 427    |
| 913         | 460             | 09/26/2013                     |                | Dx        | 82003 |      | Ortho              | 1     | Fracture Base Femoral Nck Closed          |                        |             |     |                  | TEDN   | 428    |
| 914         | 460             | 09/26/2013                     |                | Px        | 99213 |      | Ortho              | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                  | TEDN   | 428    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 915         | 460             | 09/26/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 429    |
| 916         | 460             | 09/26/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 429    |
| 917         | 460             | 09/26/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 429    |
| 918         | 460             | 09/26/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 429    |
| 919         | 460             | 09/26/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 429    |
| 920         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 430    |
| 921         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7197  |      |                    | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 430    |
| 922         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 72887 |      |                    | 3     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 430    |
| 923         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | V5409 |      |                    | 4     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 430    |
| 924         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7291  |      |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 430    |
| 925         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 725   |      |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 430    |
| 926         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7102  |      |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 430    |
| 927         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 33829 |      |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 430    |
| 928         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 73300 |      |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 430    |
| 929         | 466             | 10/02/2013                     |                | Dx        | 33818 | Inpt | Grppract           | 1     | Other Acute Postoperative Pain            |                        |             |     |                  | TEDN   | 431    |
| 930         | 466             | 10/02/2013                     |                | Dx        | 71945 | Inpt | Grppract           | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 431    |
| 931         | 466             | 10/02/2013                     |                | Px        | 62311 | Inpt | Grppract           | 1     | Njx Dx/Ther Sbst Epidural/Subarach Lumbar |                        |             |     |                  | TEDN   | 431    |
| 932         | 466             | 10/02/2013                     |                | Dx        | 8082  | Inpt | Grppract           | 1     | Closed Fracture Pubis                     |                        |             |     |                  | TEDN   | 432    |
| 933         | 466             | 10/02/2013                     |                | Dx        | 82100 | Inpt | Grppract           | 2     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 432    |
| 934         | 466             | 10/02/2013                     |                | Dx        | V4364 | Inpt | Grppract           | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 432    |
| 935         | 466             | 10/02/2013                     |                | Px        | 72170 | Inpt | Grppract           | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 432    |
| 936         | 466             | 10/02/2013                     |                | Dx        | 99640 | Inpt | Ortho              | 1     | Unsp Malfun Int Orthpd Device/Grf         |                        |             |     |                  | TEDN   | 433    |
| 937         | 466             | 10/02/2013                     |                | Px        | 27138 | Inpt | Ortho              | 1     | Revj Tot Hip Arthrp Fem Only W/Wo Algrft  |                        |             |     |                  | TEDN   | 433    |
| 938         | 466             | 10/02/2013                     |                | Dx        | 99647 | Inpt | Grppract           | 1     | Other Malfun Prosthetic Joint             |                        |             |     |                  | TEDN   | 434    |
| 939         | 466             | 10/02/2013                     |                | Dx        | 4019  | Inpt | Grppract           | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 434    |
| 940         | 466             | 10/02/2013                     |                | Dx        | 41400 | Inpt | Grppract           | 3     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 434    |
| 941         | 466             | 10/02/2013                     |                | Dx        | 2449  | Inpt | Grppract           | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 434    |
| 942         | 466             | 10/02/2013                     |                | Px        | 01215 | Inpt | Grppract           | 1     | Anesthesia Open Revision Total Hip Arthro |                        |             |     |                  | TEDN   | 434    |
| 943         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 436    |
| 944         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | V5409 |      |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 436    |
| 945         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7197  |      |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 436    |
| 946         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 72887 |      |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 436    |
| 947         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7291  |      |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 436    |
| 948         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 725   |      |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 436    |
| 949         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7102  |      |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 436    |
| 950         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 33829 |      |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 436    |
| 951         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 73300 |      |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 436    |
| 952         | 468             | 10/04/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 435    |
| 953         | 468             | 10/04/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 435    |
| 954         | 468             | 10/04/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 435    |
| 955         | 468             | 10/04/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 435    |
| 956         | 468             | 10/04/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 435    |
| 957         | 471             | 10/07/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 437    |
| 958         | 471             | 10/07/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 437    |
| 959         | 471             | 10/07/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 437    |



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| 960         | 471             | 10/07/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 437    |
| 961         | 471             | 10/07/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 437    |
| 962         | 474             | 10/10/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 438    |
| 963         | 474             | 10/10/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 438    |
| 964         | 474             | 10/10/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 438    |
| 965         | 474             | 10/10/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 438    |
| 966         | 474             | 10/10/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 438    |
| 967         | 479             | 10/15/2013                     |                | Dx        | 99677 |     | Ortho              | 1     | Complication Ot Joint Prost               |                        |             |     |                  | TEDN   | 439    |
| 968         | 479             | 10/15/2013                     |                | Dx        | 71945 |     | Ortho              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 439    |
| 969         | 479             | 10/15/2013                     |                | Dx        | V5481 |     | Ortho              | 3     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 439    |
| 970         | 479             | 10/15/2013                     |                | Dx        | V4364 |     | Ortho              | 4     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 439    |
| 971         | 479             | 10/15/2013                     |                | Px        | 72170 |     | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 439    |
| 972         | 479             | 10/15/2013                     |                | Px        | 73500 |     | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 440    |
| 973         | 482             | 10/18/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 441    |
| 974         | 482             | 10/18/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 441    |
| 975         | 482             | 10/18/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 441    |
| 976         | 482             | 10/18/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 441    |
| 977         | 482             | 10/18/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 441    |
| 978         | 484             | 10/20/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 442    |
| 979         | 484             | 10/20/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 442    |
| 980         | 484             | 10/20/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 442    |
| 981         | 484             | 10/20/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 442    |
| 982         | 484             | 10/20/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 442    |
| 983         | 487             | 10/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 443    |
| 984         | 487             | 10/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 443    |
| 985         | 487             | 10/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 444    |
| 986         | 491             | 10/27/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 445    |
| 987         | 491             | 10/27/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 445    |
| 988         | 491             | 10/27/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 445    |
| 989         | 491             | 10/27/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 445    |
| 990         | 491             | 10/27/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 445    |
| 991         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | V5789 |     |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 448    |
| 992         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | V5409 |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 448    |
| 993         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7197  |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 448    |
| 994         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 72887 |     |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 448    |
| 995         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7291  |     |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 448    |
| 996         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 725   |     |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 448    |
| 997         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7102  |     |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 448    |
| 998         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 33829 |     |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 448    |
| 999         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 73300 |     |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 448    |
| 1000        | 496             | 11/01/2013                     |                | Dx        | 3090  |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                  | TEDN   | 446    |
| 1001        | 496             | 11/01/2013                     |                | Px        | 90832 |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                  | TEDN   | 446    |
| 1002        | 496             | 11/01/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 447    |
| 1003        | 496             | 11/01/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 447    |
| 1004        | 496             | 11/01/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 447    |
| 1005        | 496             | 11/01/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 447    |



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| 1006        | 496             | 11/01/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 447    |
| 1007        | 502             | 11/07/2013                     |                | Dx        | 3090        |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                               | TEDN   | 449    |
| 1008        | 502             | 11/07/2013                     |                | Px        | 90832       |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                               | TEDN   | 449    |
| 1009        | 503             | 11/08/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 450    |
| 1010        | 503             | 11/08/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 450    |
| 1011        | 503             | 11/08/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 450    |
| 1012        | 503             | 11/08/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 450    |
| 1013        | 503             | 11/08/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 450    |
| 1014        | 506             | 11/11/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 451    |
| 1015        | 506             | 11/11/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 451    |
| 1016        | 506             | 11/11/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 451    |
| 1017        | 506             | 11/11/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 451    |
| 1018        | 506             | 11/11/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 451    |
| 1019        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 56211       |     |                    | 1     | Diverticulitis Colon                      |                        |             |     |                               | TEDI   | 452    |
| 1020        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | V5409       |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                               | TEDI   | 452    |
| 1021        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7197        |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                               | TEDI   | 452    |
| 1022        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 72887       |     |                    | 4     | Muscle Weakness                           |                        |             |     |                               | TEDI   | 452    |
| 1023        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7291        |     |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                               | TEDI   | 452    |
| 1024        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 725         |     |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDI   | 452    |
| 1025        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7102        |     |                    | 7     | Sicca Syndrome                            |                        |             |     |                               | TEDI   | 452    |
| 1026        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 33829       |     |                    | 8     | Other Chronic Pain                        |                        |             |     |                               | TEDI   | 452    |
| 1027        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 73300       |     |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                               | TEDI   | 452    |
| 1028        | 510             | 11/15/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 453    |
| 1029        | 510             | 11/15/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 453    |
| 1030        | 510             | 11/15/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 453    |
| 1031        | 510             | 11/15/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 453    |
| 1032        | 510             | 11/15/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 453    |
| 1033        | 512             | 11/17/2013                     |                | Dx        | 3090        |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                               | TEDN   | 454    |
| 1034        | 512             | 11/17/2013                     |                | Px        | 90832       |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                               | TEDN   | 454    |
| 1035        | 512             | 11/17/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 455    |
| 1036        | 512             | 11/17/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 455    |
| 1037        | 512             | 11/17/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 455    |
| 1038        | 512             | 11/17/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 455    |
| 1039        | 512             | 11/17/2013                     |                | Px        | 99315       |     | Gp                 | 1     | Nursing Facility Discharge Management 30  |                        |             |     |                               | TEDN   | 455    |
| 1040        | 518             | 11/23/2013                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 456    |
| 1041        | 518             | 11/23/2013                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 456    |
| 1042        | 518             | 11/23/2013                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 457    |
| 1043        | 520             | 11/25/2013                     |                | Dx        | V5409       |     | Medic              | 1     | Other Aftercare Internal Fix Device       |                        |             |     |                               | TEDN   | 458    |
| 1044        | 520             | 11/25/2013                     |                | Dx        | 7197        |     | Medic              | 2     | Difficulty In Walking                     |                        |             |     |                               | TEDN   | 458    |
| 1045        | 520             | 11/25/2013                     |                | Px        | K0001       |     | Medic              | 1     | Standard Wheelchair                       |                        |             |     |                               | TEDN   | 458    |
| 1046        | 522             | 11/27/2013                     |                | Rx        | 00378623305 |     |                    |       |                                           | Citalopram Hbr         | 90          | 90  | Tablet                        | PDTS   | 459    |
| 1047        | 522             | 11/27/2013                     |                | Rx        | 51672402803 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                        | PDTS   | 460    |
| 1048        | 522             | 11/27/2013                     |                | Rx        | 68180075103 |     |                    |       |                                           | Amlodipine Besylate    | 90          | 90  | Tablet                        | PDTS   | 461    |
| 1049        | 522             | 11/27/2013                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 90          | 90  | Tablet, SR,particles/Crystals | PDTS   | 462    |
| 1050        | 522             | 11/27/2013                     |                | Rx        | 62175018146 |     |                    |       |                                           | Pantoprazole Sodium    | 90          | 90  | Tablet, DR (Enteric Coated)   | PDTS   | 463    |
| 1051        | 522             | 11/27/2013                     |                | Rx        | 68180051503 |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 464    |

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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code             | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description       | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 1052        | 522             | 11/27/2013                     |                | Rx        | 00054472831      |     |                    |       |                                            | Prednisone             | 70          | 105 | Tablet           | PDTS   | 465    |
| 1053        | 522             | 11/27/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                            | INDEX STUDY DRUG       | 90          |     | INITIAL FILL     | PDTS   | 466    |
| 1054        | 523             | 11/28/2013                     |                | Dx        | 7812             |     | Intmed             | 1     | Abnormality Of Gait                        |                        |             |     |                  | TEDN   | 467    |
| 1055        | 523             | 11/28/2013                     |                | Px        | G0180            |     | Intmed             | 1     | Md Certification Hha Patient               |                        |             |     |                  | TEDN   | 467    |
| 1056        | 531             | 12/06/2013                     |                | Dx        | 4371             |     | Grpract            | 1     | Oth Generalized Ischemic Cv Disease        |                        |             |     |                  | TEDN   | 468    |
| 1057        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Grpract            | 2     | Headache                                   |                        |             |     |                  | TEDN   | 468    |
| 1058        | 531             | 12/06/2013                     |                | Dx        | 3319             |     | Grpract            | 3     | Uns Cerebral Degeneration                  |                        |             |     |                  | TEDN   | 468    |
| 1059        | 531             | 12/06/2013                     |                | Px        | 70450            |     | Grpract            | 1     | Ct Head/Brain W/O Contrast Material        |                        |             |     |                  | TEDN   | 468    |
| 1060        | 531             | 12/06/2013                     |                | Dx        | 7245             |     | Ambul              | 1     | Backache Unspecified                       |                        |             |     |                  | TEDN   | 469    |
| 1061        | 531             | 12/06/2013                     |                | Px        | A0425            |     | Ambul              | 1     | Ground Mileage                             |                        |             |     |                  | TEDN   | 469    |
| 1062        | 531             | 12/06/2013                     |                | Px        | A0427            |     | Ambul              | 1     | Als1-Emergency                             |                        |             |     |                  | TEDN   | 470    |
| 1063        | 531             | 12/06/2013                     |                | Dx        | 7245             |     | Facility           | 1     | Backache Unspecified                       |                        |             |     |                  | TEDN   | 471    |
| 1064        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Facility           | 2     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 471    |
| 1065        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Facility           | 3     | Headache                                   |                        |             |     |                  | TEDN   | 471    |
| 1066        | 531             | 12/06/2013                     |                | Dx        | 73313            |     | Facility           | 4     | Pathological Fracture Vertebrae            |                        |             |     |                  | TEDN   | 471    |
| 1067        | 531             | 12/06/2013                     |                | Dx        | V5861            |     | Facility           | 5     | Encounter Long Term Anticoagulant          |                        |             |     |                  | TEDN   | 471    |
| 1068        | 531             | 12/06/2013                     |                | Dx        | 7102             |     | Facility           | 6     | Sicca Syndrome                             |                        |             |     |                  | TEDN   | 471    |
| 1069        | 531             | 12/06/2013                     |                | Dx        | 53081            |     | Facility           | 7     | Esophageal Reflux                          |                        |             |     |                  | TEDN   | 471    |
| 1070        | 531             | 12/06/2013                     |                | Dx        | 2724             |     | Facility           | 8     | Oth/Uns Hyperlipidemia                     |                        |             |     |                  | TEDN   | 471    |
| 1071        | 531             | 12/06/2013                     |                | Px        | 36415            |     | Facility           | 1     | Collection Venous Blood Venipuncture       |                        |             |     |                  | TEDN   | 471    |
| 1072        | 531             | 12/06/2013                     |                | Px        | 70450            |     | Facility           | 1     | Ct Head/Brain W/O Contrast Material        |                        |             |     |                  | TEDN   | 472    |
| 1073        | 531             | 12/06/2013                     |                | Px        | 71020            |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat  |                        |             |     |                  | TEDN   | 473    |
| 1074        | 531             | 12/06/2013                     |                | Px        | 80048            |     | Facility           | 1     | Basic Metabolic Panel Calcium Total        |                        |             |     |                  | TEDN   | 474    |
| 1075        | 531             | 12/06/2013                     |                | Px        | 83735            |     | Facility           | 1     | Magnesium                                  |                        |             |     |                  | TEDN   | 475    |
| 1076        | 531             | 12/06/2013                     |                | Px        | 84484            |     | Facility           | 1     | Troponin Quantitative                      |                        |             |     |                  | TEDN   | 476    |
| 1077        | 531             | 12/06/2013                     |                | Px        | 85025            |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb  |                        |             |     |                  | TEDN   | 477    |
| 1078        | 531             | 12/06/2013                     |                | Px        | 85610            |     | Facility           | 1     | Prothrombin Time                           |                        |             |     |                  | TEDN   | 478    |
| 1079        | 531             | 12/06/2013                     |                | Px        | 93005            |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only   |                        |             |     |                  | TEDN   | 479    |
| 1080        | 531             | 12/06/2013                     |                | Px        | 96374            |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbstd |                        |             |     |                  | TEDN   | 480    |
| 1081        | 531             | 12/06/2013                     |                | Px        | 99285            |     | Facility           | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                  | TEDN   | 481    |
| 1082        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Gp                 | 1     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 482    |
| 1083        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Gp                 | 2     | Headache                                   |                        |             |     |                  | TEDN   | 482    |
| 1084        | 531             | 12/06/2013                     |                | Dx        | 8052             |     | Gp                 | 3     | Fracture Dorsal Vertebra Close             |                        |             |     |                  | TEDN   | 482    |
| 1085        | 531             | 12/06/2013                     |                | Px        | 93010            |     | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only    |                        |             |     |                  | TEDN   | 482    |
| 1086        | 531             | 12/06/2013                     |                | Px        | 99285            |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                  | TEDN   | 483    |
| 1087        | 531             | 12/06/2013                     |                | Dx        | 8052             |     | Radio              | 1     | Fracture Dorsal Vertebra Close             |                        |             |     |                  | TEDN   | 484    |
| 1088        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Radio              | 2     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 484    |
| 1089        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Radio              | 3     | Headache                                   |                        |             |     |                  | TEDN   | 484    |
| 1090        | 531             | 12/06/2013                     |                | Dx        | E9289            |     | Radio              | 4     | Uns Accident                               |                        |             |     |                  | TEDN   | 484    |
| 1091        | 531             | 12/06/2013                     |                | Px        | 71020            |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat  |                        |             |     |                  | TEDN   | 484    |
| 1092        | 535             | 12/10/2013                     |                | Rx        | 65162062750      |     |                    |       |                                            | Tramadol Hcl           | 33          | 100 | Tablet           | PDTS   | 485    |
| 1093        | 542             | 12/17/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                  | TEDN   | 486    |
| 1094        | 542             | 12/17/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                  | TEDN   | 486    |
| 1095        | 542             | 12/17/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                  | TEDN   | 486    |
| 1096        | 542             | 12/17/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                  | TEDN   | 487    |
| 1097        | 545             | 12/20/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                  | TEDN   | 488    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 1098        | 545             | 12/20/2013                     |                | Px        | 85610 |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 488    |
| 1099        | 545             | 12/20/2013                     |                | Px        | 99211 |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 489    |
| 1100        | 548             | 12/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 490    |
| 1101        | 548             | 12/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 490    |
| 1102        | 548             | 12/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 491    |
| 1103        | 550             | 12/25/2013                     |                | Dx        | V5409 |     | Medic              | 1     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDN   | 492    |
| 1104        | 550             | 12/25/2013                     |                | Dx        | 7197  |     | Medic              | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDN   | 492    |
| 1105        | 550             | 12/25/2013                     |                | Px        | K0001 |     | Medic              | 1     | Standard Wheelchair                       |                        |             |     |                  | TEDN   | 492    |
| 1106        | 570             | 01/14/2014                     |                | Dx        | 8470  |     | Gp                 | 1     | Sprain/Strain Of Neck                     |                        |             |     |                  | TEDN   | 493    |
| 1107        | 570             | 01/14/2014                     |                | Dx        | 92401 |     | Gp                 | 2     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 493    |
| 1108        | 570             | 01/14/2014                     |                | Dx        | 2859  |     | Gp                 | 3     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 493    |
| 1109        | 570             | 01/14/2014                     |                | Dx        | E8129 |     | Gp                 | 4     | Mva Collis Unsp Pers Unspec               |                        |             |     |                  | TEDN   | 493    |
| 1110        | 570             | 01/14/2014                     |                | Px        | 99285 |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 493    |
| 1111        | 570             | 01/14/2014                     |                | Dx        | 92401 |     | Grppract           | 1     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 494    |
| 1112        | 570             | 01/14/2014                     |                | Dx        | 2859  |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 494    |
| 1113        | 570             | 01/14/2014                     |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 494    |
| 1114        | 570             | 01/14/2014                     |                | Dx        | 41400 |     | Grppract           | 4     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 494    |
| 1115        | 570             | 01/14/2014                     |                | Px        | 99220 |     | Grppract           | 1     | Initial Observation Care/Day High Severit |                        |             |     |                  | TEDN   | 494    |
| 1116        | 570             | 01/14/2014                     |                | Dx        | 95901 |     | Radio              | 1     | Uns Head Injury                           |                        |             |     |                  | TEDN   | 495    |
| 1117        | 570             | 01/14/2014                     |                | Dx        | 3319  |     | Radio              | 2     | Uns Cerebral Degeneration                 |                        |             |     |                  | TEDN   | 495    |
| 1118        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 3     | Uns Accident                              |                        |             |     |                  | TEDN   | 495    |
| 1119        | 570             | 01/14/2014                     |                | Px        | 70450 |     | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 495    |
| 1120        | 570             | 01/14/2014                     |                | Dx        | 95909 |     | Radio              | 1     | Injury Face/Neck                          |                        |             |     |                  | TEDN   | 496    |
| 1121        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 2     | Uns Accident                              |                        |             |     |                  | TEDN   | 496    |
| 1122        | 570             | 01/14/2014                     |                | Px        | 72020 |     | Radio              | 1     | Radex Spine 1 View Specify Level          |                        |             |     |                  | TEDN   | 496    |
| 1123        | 570             | 01/14/2014                     |                | Px        | 72050 |     | Radio              | 1     | Radex Spine Cervical Minimum 4 Views      |                        |             |     |                  | TEDN   | 497    |
| 1124        | 570             | 01/14/2014                     |                | Dx        | 9596  |     | Radio              | 1     | Oth/Uns Injury Hip/Thigh                  |                        |             |     |                  | TEDN   | 498    |
| 1125        | 570             | 01/14/2014                     |                | Dx        | 95919 |     | Radio              | 2     | Other Injury Other Sites Of Trunk         |                        |             |     |                  | TEDN   | 498    |
| 1126        | 570             | 01/14/2014                     |                | Dx        | V4364 |     | Radio              | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 498    |
| 1127        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 4     | Uns Accident                              |                        |             |     |                  | TEDN   | 498    |
| 1128        | 570             | 01/14/2014                     |                | Px        | 72170 |     | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 498    |
| 1129        | 570             | 01/14/2014                     |                | Dx        | 9596  |     | Radio              | 1     | Oth/Uns Injury Hip/Thigh                  |                        |             |     |                  | TEDN   | 499    |
| 1130        | 570             | 01/14/2014                     |                | Dx        | V4364 |     | Radio              | 2     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 499    |
| 1131        | 570             | 01/14/2014                     |                | Dx        | E8199 |     | Radio              | 3     | Mva Uns Injuring Uns Person               |                        |             |     |                  | TEDN   | 499    |
| 1132        | 570             | 01/14/2014                     |                | Px        | 73510 |     | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                  | TEDN   | 499    |
| 1133        | 571             | 01/15/2014                     |                | Dx        | 92401 |     | Grppract           | 1     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 500    |
| 1134        | 571             | 01/15/2014                     |                | Dx        | 2859  |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 500    |
| 1135        | 571             | 01/15/2014                     |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 500    |
| 1136        | 571             | 01/15/2014                     |                | Dx        | 41400 |     | Grppract           | 4     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 500    |
| 1137        | 571             | 01/15/2014                     |                | Px        | 99225 |     | Grppract           | 1     | Sbsq Observation Care/Day Moderate Severi |                        |             |     |                  | TEDN   | 500    |

End of Profile



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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|--------------------------------------|-------------------------|-------------|-----|----------------------------|--------|--------|
| 1           | -363            | 11/03/2012                     |                | Dx        | 4659        |      | Fp                 | 1     | Acute Upper Resp Infections Uns      |                         |             |     |                            | TEDN   | 3      |
| 2           | -363            | 11/03/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes   |                         |             |     |                            | TEDN   | 3      |
| 3           | -363            | 11/03/2012                     |                | Rx        | 00781149668 |      |                    |       |                                      | Azithromycin            | 8           | 12  | Tablet                     | PDTS   | 1      |
| 4           | -363            | 11/03/2012                     |                | Rx        | 00603158854 |      |                    |       |                                      | Promethazine Vc-Codeine | 10          | 4   | Syrup                      | PDTS   | 2      |
| 5           | -354            | 11/12/2012                     |                | Rx        | 00603158854 |      |                    |       |                                      | Promethazine Vc-Codeine | 10          | 4   | Syrup                      | PDTS   | 4      |
| 6           | -354            | 11/12/2012                     |                | Rx        | 13668000810 |      |                    |       |                                      | Zolpidem Tartrate       | 30          | 30  | Tablet                     | PDTS   | 5      |
| 7           | -351            | 11/15/2012                     |                | Dx        | 4610        |      | Fp                 | 1     | Acute Maxillary Sinusitis            |                         |             |     |                            | TEDN   | 8      |
| 8           | -351            | 11/15/2012                     |                | Dx        | 71946       |      | Fp                 | 2     | Pain In Joint Lower Leg              |                         |             |     |                            | TEDN   | 8      |
| 9           | -351            | 11/15/2012                     |                | Dx        | 4659        |      | Fp                 | 3     | Acute Upper Resp Infections Uns      |                         |             |     |                            | TEDN   | 8      |
| 10          | -351            | 11/15/2012                     |                | Dx        | 460         |      | Fp                 | 4     | Acute Nasopharyngitis                |                         |             |     |                            | TEDN   | 8      |
| 11          | -351            | 11/15/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes   |                         |             |     |                            | TEDN   | 8      |
| 12          | -351            | 11/15/2012                     |                | Rx        | 59762306001 |      |                    |       |                                      | Azithromycin            | 5           | 12  | Tablet                     | PDTS   | 6      |
| 13          | -351            | 11/15/2012                     |                | Rx        | 00525801990 |      |                    |       |                                      | Metanx                  | 30          | 60  | Tablet                     | PDTS   | 7      |
| 14          | -347            | 11/19/2012                     |                | Dx        | 25060       |      | Podia              | 1     | Diabetes Neuro Manif Type Ii         |                         |             |     |                            | TEDN   | 9      |
| 15          | -347            | 11/19/2012                     |                | Dx        | 1101        |      | Podia              | 2     | Dermatophytosis Nail                 |                         |             |     |                            | TEDN   | 9      |
| 16          | -347            | 11/19/2012                     |                | Dx        | 7812        |      | Podia              | 3     | Abnormality Of Gait                  |                         |             |     |                            | TEDN   | 9      |
| 17          | -347            | 11/19/2012                     |                | Px        | 11721       |      | Podia              | 1     | Debridement Nail Any Method 6/>      |                         |             |     |                            | TEDN   | 9      |
| 18          | -337            | 11/29/2012                     |                | Rx        | 49884040401 |      |                    |       |                                      | Metoprolol Succinate    | 90          | 90  | Tablet, SR 24hr            | PDTS   | 10     |
| 19          | -337            | 11/29/2012                     |                | Rx        | 63653117105 |      |                    |       |                                      | Plavix                  | 90          | 90  | Tablet                     | PDTS   | 11     |
| 20          | -337            | 11/29/2012                     |                | Rx        | 00078037905 |      |                    |       |                                      | Lotrel                  | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 12     |
| 21          | -337            | 11/29/2012                     |                | Rx        | 53746025310 |      |                    |       |                                      | Ranitidine Hcl          | 90          | 360 | Tablet                     | PDTS   | 13     |
| 22          | -337            | 11/29/2012                     |                | Rx        | 00071015823 |      |                    |       |                                      | Lipitor                 | 90          | 90  | Tablet                     | PDTS   | 14     |
| 23          | -337            | 11/29/2012                     |                | Rx        | 00904584940 |      |                    |       |                                      | Metformin Hcl           | 90          | 90  | Tablet                     | PDTS   | 15     |
| 24          | -337            | 11/29/2012                     |                | Rx        | 50111032703 |      |                    |       |                                      | Hydralazine Hcl         | 90          | 180 | Tablet                     | PDTS   | 16     |
| 25          | -327            | 12/09/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 17     |
| 26          | -327            | 12/09/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 17     |
| 27          | -327            | 12/09/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 17     |
| 28          | -327            | 12/09/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 17     |
| 29          | -327            | 12/09/2012                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes |                         |             |     |                            | TEDN   | 17     |
| 30          | -326            | 12/10/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 18     |
| 31          | -326            | 12/10/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 18     |
| 32          | -326            | 12/10/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 18     |
| 33          | -326            | 12/10/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 18     |
| 34          | -326            | 12/10/2012                     |                | Px        | 99233       | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes    |                         |             |     |                            | TEDN   | 18     |
| 35          | -325            | 12/11/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 19     |
| 36          | -325            | 12/11/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 19     |
| 37          | -325            | 12/11/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 19     |
| 38          | -325            | 12/11/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 19     |
| 39          | -325            | 12/11/2012                     |                | Px        | 99232       | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes    |                         |             |     |                            | TEDN   | 19     |
| 40          | -324            | 12/12/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 20     |
| 41          | -324            | 12/12/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 20     |
| 42          | -324            | 12/12/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 20     |
| 43          | -324            | 12/12/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 20     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|------------------|--------|--------|
| 44          | -324            | 12/12/2012                     |                | Px        | 99238       | Inpt | Fp                 | 1     | Hospital Discharge Day Management 30 Min/ |                            |             |     |                  | TEDN   | 20     |
| 45          | -323            | 12/13/2012                     |                | Dx        | 78052       |      | Fp                 | 1     | Insomnia Unspecified                      |                            |             |     |                  | TEDN   | 23     |
| 46          | -323            | 12/13/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 23     |
| 47          | -323            | 12/13/2012                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 21     |
| 48          | -323            | 12/13/2012                     |                | Rx        | 00525801990 |      |                    |       |                                           | Metanx                     | 30          | 60  | Tablet           | PDTS   | 22     |
| 49          | -319            | 12/17/2012                     |                | Dx        | 41401       |      | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                  | TEDN   | 24     |
| 50          | -319            | 12/17/2012                     |                | Dx        | 4011        |      | Cardvasc           | 2     | Benign Essential Hypertension             |                            |             |     |                  | TEDN   | 24     |
| 51          | -319            | 12/17/2012                     |                | Dx        | 2722        |      | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                            |             |     |                  | TEDN   | 24     |
| 52          | -319            | 12/17/2012                     |                | Dx        | 25000       |      | Cardvasc           | 4     | Diabetes Uncompl Type li                  |                            |             |     |                  | TEDN   | 24     |
| 53          | -319            | 12/17/2012                     |                | Px        | 99214       |      | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                  | TEDN   | 24     |
| 54          | -316            | 12/20/2012                     |                | Dx        | 7859        |      | Grpprac            | 1     | Other Cardiovascular Symptoms             |                            |             |     |                  | TEDN   | 25     |
| 55          | -316            | 12/20/2012                     |                | Px        | 93880       |      | Grpprac            | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                            |             |     |                  | TEDN   | 25     |
| 56          | -316            | 12/20/2012                     |                | Dx        | 7859        |      | Facility           | 1     | Other Cardiovascular Symptoms             |                            |             |     |                  | TEDN   | 26     |
| 57          | -316            | 12/20/2012                     |                | Px        | 93880       |      | Facility           | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                            |             |     |                  | TEDN   | 26     |
| 58          | -309            | 12/27/2012                     |                | Rx        | 00168025846 |      |                    |       |                                           | Clotrimazole-Betamethasone | 10          | 45  | Cream (Grams)    | PDTS   | 27     |
| 59          | -305            | 12/31/2012                     |                | Dx        | 460         |      | Grpprac            | 1     | Acute Nasopharyngitis                     |                            |             |     |                  | TEDN   | 31     |
| 60          | -305            | 12/31/2012                     |                | Dx        | 4610        |      | Grpprac            | 2     | Acute Maxillary Sinusitis                 |                            |             |     |                  | TEDN   | 31     |
| 61          | -305            | 12/31/2012                     |                | Px        | 99213       |      | Grpprac            | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 31     |
| 62          | -305            | 12/31/2012                     |                | Rx        | 00603158854 |      |                    |       |                                           | Promethazine Vc-Codeine    | 8           | 120 | Syrup            | PDTS   | 28     |
| 63          | -305            | 12/31/2012                     |                | Rx        | 65862001501 |      |                    |       |                                           | Amoxicillin                | 10          | 20  | Tablet           | PDTS   | 29     |
| 64          | -305            | 12/31/2012                     |                | Rx        | 00603307932 |      |                    |       |                                           | Cyclobenzaprine Hcl        | 10          | 30  | Tablet           | PDTS   | 30     |
| 65          | -291            | 01/14/2013                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 32     |
| 66          | -283            | 01/22/2013                     |                | Dx        | 4610        |      | Fp                 | 1     | Acute Maxillary Sinusitis                 |                            |             |     |                  | TEDN   | 35     |
| 67          | -283            | 01/22/2013                     |                | Dx        | 460         |      | Fp                 | 2     | Acute Nasopharyngitis                     |                            |             |     |                  | TEDN   | 35     |
| 68          | -283            | 01/22/2013                     |                | Dx        | 4659        |      | Fp                 | 3     | Acute Upper Resp Infections Uns           |                            |             |     |                  | TEDN   | 35     |
| 69          | -283            | 01/22/2013                     |                | Dx        | 4660        |      | Fp                 | 4     | Acute Bronchitis                          |                            |             |     |                  | TEDN   | 35     |
| 70          | -283            | 01/22/2013                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 35     |
| 71          | -283            | 01/22/2013                     |                | Rx        | 57664037718 |      |                    |       |                                           | Tramadol Hcl               | 14          | 56  | Tablet           | PDTS   | 33     |
| 72          | -283            | 01/22/2013                     |                | Rx        | 00603158858 |      |                    |       |                                           | Promethazine Vc-Codeine    | 12          | 60  | Syrup            | PDTS   | 34     |
| 73          | -275            | 01/30/2013                     |                | Dx        | 41401       |      | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                  | TEDN   | 36     |
| 74          | -275            | 01/30/2013                     |                | Px        | 78452       |      | Cardvasc           | 1     | Myocardial Spect Multiple Studies         |                            |             |     |                  | TEDN   | 36     |
| 75          | -275            | 01/30/2013                     |                | Px        | 93016       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Phys Sup |                            |             |     |                  | TEDN   | 37     |
| 76          | -275            | 01/30/2013                     |                | Px        | 93017       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Trcg Onl |                            |             |     |                  | TEDN   | 38     |
| 77          | -275            | 01/30/2013                     |                | Px        | 93018       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg I&r Only |                            |             |     |                  | TEDN   | 39     |
| 78          | -275            | 01/30/2013                     |                | Px        | A9502       |      | Cardvasc           | 1     | Tc99m Tetrofosmin                         |                            |             |     |                  | TEDN   | 40     |
| 79          | -267            | 02/07/2013                     |                | Dx        | 8448        |      | Ortho              | 1     | Sprain/Strain Of Knee/Leg Ot              |                            |             |     |                  | TEDN   | 41     |
| 80          | -267            | 02/07/2013                     |                | Dx        | 71514       |      | Ortho              | 2     | Osteoarthritis Local Prim Hand            |                            |             |     |                  | TEDN   | 41     |
| 81          | -267            | 02/07/2013                     |                | Px        | 20600       |      | Ortho              | 1     | Arthrocentesis Aspir&/Injection Small Jt/ |                            |             |     |                  | TEDN   | 41     |
| 82          | -267            | 02/07/2013                     |                | Px        | 99214       |      | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                  | TEDN   | 42     |
| 83          | -267            | 02/07/2013                     |                | Px        | J3301       |      | Ortho              | 1     | Triamcinolone Acet Inj Nos                |                            |             |     |                  | TEDN   | 43     |
| 84          | -261            | 02/13/2013                     |                | Dx        | 71946       |      | Grpprac            | 1     | Pain In Joint Lower Leg                   |                            |             |     |                  | TEDN   | 44     |
| 85          | -261            | 02/13/2013                     |                | Px        | 73562       |      | Grpprac            | 1     | Radiologic Examination Knee 3 Views       |                            |             |     |                  | TEDN   | 44     |
| 86          | -259            | 02/15/2013                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 45     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|---------------------------|-------------|-----|----------------------------|--------|--------|
| 87          | -259            | 02/15/2013                     |                | Rx        | 00591034905 |     |                    |       |                                           | Hydrocodone-Acetaminophen | 15          | 90  | Tablet                     | PDTS   | 46     |
| 88          | -252            | 02/22/2013                     |                | Rx        | 00591551310 |     |                    |       |                                           | Carisoprodol              | 10          | 10  | Tablet                     | PDTS   | 47     |
| 89          | -243            | 03/03/2013                     |                | Dx        | 8472        |     | Fp                 | 1     | Sprain/Strain Lumbar Region               |                           |             |     |                            | TEDN   | 51     |
| 90          | -243            | 03/03/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                            | TEDN   | 51     |
| 91          | -243            | 03/03/2013                     |                | Rx        | 29300012510 |     |                    |       |                                           | Meloxicam                 | 30          | 30  | Tablet                     | PDTS   | 48     |
| 92          | -243            | 03/03/2013                     |                | Rx        | 57664037718 |     |                    |       |                                           | Tramadol Hcl              | 12          | 50  | Tablet                     | PDTS   | 49     |
| 93          | -243            | 03/03/2013                     |                | Rx        | 00591551310 |     |                    |       |                                           | Carisoprodol              | 30          | 50  | Tablet                     | PDTS   | 50     |
| 94          | -227            | 03/19/2013                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                           |             |     |                            | TEDN   | 52     |
| 95          | -227            | 03/19/2013                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                           |             |     |                            | TEDN   | 52     |
| 96          | -227            | 03/19/2013                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                           |             |     |                            | TEDN   | 52     |
| 97          | -227            | 03/19/2013                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type Ii                  |                           |             |     |                            | TEDN   | 52     |
| 98          | -227            | 03/19/2013                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                            | TEDN   | 52     |
| 99          | -223            | 03/23/2013                     |                | Rx        | 59762306001 |     |                    |       |                                           | Azithromycin              | 8           | 12  | Tablet                     | PDTS   | 53     |
| 100         | -223            | 03/23/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate         | 15          | 15  | Tablet                     | PDTS   | 54     |
| 101         | -220            | 03/26/2013                     |                | Dx        | 4659        |     | Fp                 | 1     | Acute Upper Resp Infections Uns           |                           |             |     |                            | TEDN   | 58     |
| 102         | -220            | 03/26/2013                     |                | Dx        | 4660        |     | Fp                 | 2     | Acute Bronchitis                          |                           |             |     |                            | TEDN   | 58     |
| 103         | -220            | 03/26/2013                     |                | Dx        | 4610        |     | Fp                 | 3     | Acute Maxillary Sinusitis                 |                           |             |     |                            | TEDN   | 58     |
| 104         | -220            | 03/26/2013                     |                | Dx        | 4871        |     | Fp                 | 4     | Influenza W Oth Respiratory Manif         |                           |             |     |                            | TEDN   | 58     |
| 105         | -220            | 03/26/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                            | TEDN   | 58     |
| 106         | -220            | 03/26/2013                     |                | Rx        | 00378363705 |     |                    |       |                                           | Cetirizine Hcl            | 30          | 30  | Tablet                     | PDTS   | 55     |
| 107         | -220            | 03/26/2013                     |                | Rx        | 00603158758 |     |                    |       |                                           | Promethazine Vc           | 9           | 180 | Syrup                      | PDTS   | 56     |
| 108         | -220            | 03/26/2013                     |                | Rx        | 00004080085 |     |                    |       |                                           | Tamiflu                   | 5           | 10  | Capsule (Hard, Soft, Etc.) | PDTS   | 57     |
| 109         | -219            | 03/27/2013                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate      | 90          | 90  | Tablet, SR 24hr            | PDTS   | 59     |
| 110         | -219            | 03/27/2013                     |                | Rx        | 54569214000 |     |                    |       |                                           | Nitrostat                 | 30          | 100 | Tablet, Sublingual         | PDTS   | 60     |
| 111         | -219            | 03/27/2013                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                    | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 61     |
| 112         | -219            | 03/27/2013                     |                | Rx        | 00071015823 |     |                    |       |                                           | Lipitor                   | 90          | 90  | Tablet                     | PDTS   | 62     |
| 113         | -219            | 03/27/2013                     |                | Rx        | 50111032703 |     |                    |       |                                           | Hydralazine Hcl           | 90          | 180 | Tablet                     | PDTS   | 63     |
| 114         | -219            | 03/27/2013                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl             | 90          | 90  | Tablet                     | PDTS   | 64     |
| 115         | -219            | 03/27/2013                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl            | 90          | 360 | Tablet                     | PDTS   | 65     |
| 116         | -211            | 04/04/2013                     |                | Dx        | 490         |     | Gp                 | 1     | Bronchitis Unspecified                    |                           |             |     |                            | TEDN   | 69     |
| 117         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Gp                 | 2     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 69     |
| 118         | -211            | 04/04/2013                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                           |             |     |                            | TEDN   | 69     |
| 119         | -211            | 04/04/2013                     |                | Dx        | 7862        |     | Radio              | 1     | Cough                                     |                           |             |     |                            | TEDN   | 70     |
| 120         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Radio              | 2     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 70     |
| 121         | -211            | 04/04/2013                     |                | Px        | 71020       |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                           |             |     |                            | TEDN   | 70     |
| 122         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Facility           | 1     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 71     |
| 123         | -211            | 04/04/2013                     |                | Dx        | 4660        |     | Facility           | 2     | Acute Bronchitis                          |                           |             |     |                            | TEDN   | 71     |
| 124         | -211            | 04/04/2013                     |                | Dx        | 412         |     | Facility           | 3     | Old Myocardial Infarction                 |                           |             |     |                            | TEDN   | 71     |
| 125         | -211            | 04/04/2013                     |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                           |             |     |                            | TEDN   | 71     |
| 126         | -211            | 04/04/2013                     |                | Dx        | 25000       |     | Facility           | 5     | Diabetes Uncompl Type Ii                  |                           |             |     |                            | TEDN   | 71     |
| 127         | -211            | 04/04/2013                     |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                           |             |     |                            | TEDN   | 71     |
| 128         | -211            | 04/04/2013                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                           |             |     |                            | TEDN   | 72     |
| 129         | -211            | 04/04/2013                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor  |                           |             |     |                            | TEDN   | 73     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|----------------------------|--------|--------|
| 130         | -211            | 04/04/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                            |             |     |                            | TEDN   | 74     |
| 131         | -211            | 04/04/2013                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog              |                            |             |     |                            | TEDN   | 75     |
| 132         | -211            | 04/04/2013                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 3           | 20  | Tablet                     | PDTS   | 66     |
| 133         | -211            | 04/04/2013                     |                | Rx        | 00603533832 |     |                    |       |                                           | Prednisone                 | 21          | 56  | Tablet                     | PDTS   | 67     |
| 134         | -211            | 04/04/2013                     |                | Rx        | 67877010605 |     |                    |       |                                           | Benzonatate                | 8           | 30  | Capsule (Hard, Soft, Etc.) | PDTS   | 68     |
| 135         | -207            | 04/08/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 15          | 15  | Tablet                     | PDTS   | 76     |
| 136         | -206            | 04/09/2013                     |                | Dx        | 4241        |     | Cardvasc           | 1     | Aortic Valve Disorders                    |                            |             |     |                            | TEDN   | 77     |
| 137         | -206            | 04/09/2013                     |                | Px        | 93306       |     | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                            |             |     |                            | TEDN   | 77     |
| 138         | -206            | 04/09/2013                     |                | Dx        | 4241        |     | Facility           | 1     | Aortic Valve Disorders                    |                            |             |     |                            | TEDN   | 78     |
| 139         | -206            | 04/09/2013                     |                | Dx        | 3970        |     | Facility           | 2     | Diseases Tricuspid Valve                  |                            |             |     |                            | TEDN   | 78     |
| 140         | -206            | 04/09/2013                     |                | Px        | 93306       |     | Facility           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                            |             |     |                            | TEDN   | 78     |
| 141         | -202            | 04/13/2013                     |                | Rx        | 31722022205 |     |                    |       |                                           | Gabapentin                 | 30          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 79     |
| 142         | -202            | 04/13/2013                     |                | Rx        | 00603158858 |     |                    |       |                                           | Promethazine Vc-Codeine    | 12          | 60  | Syrup                      | PDTS   | 80     |
| 143         | -186            | 04/29/2013                     |                | Dx        | 7840        |     | Fp                 | 1     | Headache                                  |                            |             |     |                            | TEDN   | 84     |
| 144         | -186            | 04/29/2013                     |                | Dx        | 53081       |     | Fp                 | 2     | Esophageal Reflux                         |                            |             |     |                            | TEDN   | 84     |
| 145         | -186            | 04/29/2013                     |                | Dx        | 78052       |     | Fp                 | 3     | Insomnia Unspecified                      |                            |             |     |                            | TEDN   | 84     |
| 146         | -186            | 04/29/2013                     |                | Dx        | 4610        |     | Fp                 | 4     | Acute Maxillary Sinusitis                 |                            |             |     |                            | TEDN   | 84     |
| 147         | -186            | 04/29/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 84     |
| 148         | -186            | 04/29/2013                     |                | Rx        | 0           |     |                    |       |                                           | Compounded Medication      | 6           | 360 |                            | PDTS   | 81     |
| 149         | -186            | 04/29/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 82     |
| 150         | -186            | 04/29/2013                     |                | Rx        | 60429002230 |     |                    |       |                                           | Amoxicillin                | 10          | 30  | Capsule (Hard, Soft, Etc.) | PDTS   | 83     |
| 151         | -176            | 05/09/2013                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)              | PDTS   | 85     |
| 152         | -162            | 05/23/2013                     |                | Rx        | 55111019605 |     |                    |       |                                           | Clopidogrel                | 60          | 60  | Tablet                     | PDTS   | 86     |
| 153         | -154            | 05/31/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 87     |
| 154         | -153            | 06/01/2013                     |                | Dx        | 25000       |     | Fp                 | 1     | Diabetes Uncompl Type Ii                  |                            |             |     |                            | TEDN   | 88     |
| 155         | -153            | 06/01/2013                     |                | Dx        | 2810        |     | Fp                 | 2     | Pernicious Anemia                         |                            |             |     |                            | TEDN   | 88     |
| 156         | -153            | 06/01/2013                     |                | Dx        | 7295        |     | Fp                 | 3     | Pain In Limb                              |                            |             |     |                            | TEDN   | 88     |
| 157         | -153            | 06/01/2013                     |                | Dx        | 7804        |     | Fp                 | 4     | Dizziness And Giddiness                   |                            |             |     |                            | TEDN   | 88     |
| 158         | -153            | 06/01/2013                     |                | Px        | 80053       |     | Fp                 | 1     | Comprehensive Metabolic Panel             |                            |             |     |                            | TEDN   | 88     |
| 159         | -153            | 06/01/2013                     |                | Px        | 83036       |     | Fp                 | 1     | Hemoglobin Glycosylated A1c               |                            |             |     |                            | TEDN   | 89     |
| 160         | -153            | 06/01/2013                     |                | Px        | 85025       |     | Fp                 | 1     | Blood Count Complete Auto&auto Difrnlt Wb |                            |             |     |                            | TEDN   | 90     |
| 161         | -153            | 06/01/2013                     |                | Px        | 99214       |     | Fp                 | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                            | TEDN   | 91     |
| 162         | -152            | 06/02/2013                     |                | Rx        | 51991060401 |     |                    |       |                                           | Vitamin D2                 | 90          | 12  | Capsule (Hard, Soft, Etc.) | PDTS   | 92     |
| 163         | -144            | 06/10/2013                     |                | Dx        | 25060       |     | Grppract           | 1     | Diabetes Neuro Manif Type Ii              |                            |             |     |                            | TEDN   | 94     |
| 164         | -144            | 06/10/2013                     |                | Dx        | 7030        |     | Grppract           | 2     | Ingrowing Nail                            |                            |             |     |                            | TEDN   | 94     |
| 165         | -144            | 06/10/2013                     |                | Dx        | 1101        |     | Grppract           | 3     | Dermatophytosis Nail                      |                            |             |     |                            | TEDN   | 94     |
| 166         | -144            | 06/10/2013                     |                | Dx        | 7823        |     | Grppract           | 4     | Edema                                     |                            |             |     |                            | TEDN   | 94     |
| 167         | -144            | 06/10/2013                     |                | Dx        | 3556        |     | Grppract           | 5     | Lesion Plantar Nerve                      |                            |             |     |                            | TEDN   | 94     |
| 168         | -144            | 06/10/2013                     |                | Dx        | 73399       |     | Grppract           | 6     | Other Disorders Bone/Cartilage            |                            |             |     |                            | TEDN   | 94     |
| 169         | -144            | 06/10/2013                     |                | Px        | 99213       |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 94     |
| 170         | -144            | 06/10/2013                     |                | Rx        | 0           |     |                    |       |                                           | Compounded Medication      | 6           | 360 |                            | PDTS   | 93     |
| 171         | -143            | 06/11/2013                     |                | Dx        | 71597       |     | Grppract           | 1     | Osteoarthritis Unsp Ankle/Foot            |                            |             |     |                            | TEDN   | 95     |
| 172         | -143            | 06/11/2013                     |                | Dx        | 71947       |     | Grppract           | 2     | Pain In Joint Ankle/Foot                  |                            |             |     |                            | TEDN   | 95     |



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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|--------------------------------------------|-----------------------------|-------------|-----|----------------------------|--------|--------|
| 173         | -143            | 06/11/2013                     |                | Px        | 73630       |     | Grpract            | 1     | Radex Foot Complete Minimum 3 Views        |                             |             |     |                            | TEDN   | 95     |
| 174         | -130            | 06/24/2013                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art            |                             |             |     |                            | TEDN   | 96     |
| 175         | -130            | 06/24/2013                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension              |                             |             |     |                            | TEDN   | 96     |
| 176         | -130            | 06/24/2013                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                       |                             |             |     |                            | TEDN   | 96     |
| 177         | -130            | 06/24/2013                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type Ii                   |                             |             |     |                            | TEDN   | 96     |
| 178         | -130            | 06/24/2013                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes         |                             |             |     |                            | TEDN   | 96     |
| 179         | -129            | 06/25/2013                     |                | Dx        | 25060       |     | Grpract            | 1     | Diabetes Neuro Manif Type Ii               |                             |             |     |                            | TEDN   | 97     |
| 180         | -129            | 06/25/2013                     |                | Dx        | 4019        |     | Grpract            | 2     | Unspecified Essential Hypertension         |                             |             |     |                            | TEDN   | 97     |
| 181         | -129            | 06/25/2013                     |                | Dx        | 78191       |     | Grpract            | 3     | Loss Of Height                             |                             |             |     |                            | TEDN   | 97     |
| 182         | -129            | 06/25/2013                     |                | Dx        | 78079       |     | Grpract            | 4     | Other Malaise And Fatigue                  |                             |             |     |                            | TEDN   | 97     |
| 183         | -129            | 06/25/2013                     |                | Px        | 99204       |     | Grpract            | 1     | Office Outpatient New 45 Minutes           |                             |             |     |                            | TEDN   | 97     |
| 184         | -127            | 06/27/2013                     |                | Rx        | 53746025310 |     |                    |       |                                            | Ranitidine Hcl              | 90          | 360 | Tablet                     | PDTS   | 98     |
| 185         | -127            | 06/27/2013                     |                | Rx        | 00904584940 |     |                    |       |                                            | Metformin Hcl               | 90          | 90  | Tablet                     | PDTS   | 99     |
| 186         | -127            | 06/27/2013                     |                | Rx        | 49884040401 |     |                    |       |                                            | Metoprolol Succinate        | 90          | 90  | Tablet, SR 24hr            | PDTS   | 100    |
| 187         | -127            | 06/27/2013                     |                | Rx        | 50111032703 |     |                    |       |                                            | Hydralazine Hcl             | 90          | 180 | Tablet                     | PDTS   | 101    |
| 188         | -123            | 07/01/2013                     |                | Rx        | 00078040605 |     |                    |       |                                            | Lotrel                      | 90          | 180 | Capsule (Hard, Soft, Etc.) | PDTS   | 102    |
| 189         | -122            | 07/02/2013                     |                | Rx        | 00603646832 |     |                    |       |                                            | Zolpidem Tartrate           | 30          | 30  | Tablet                     | PDTS   | 103    |
| 190         | -116            | 07/08/2013                     |                | Dx        | 25060       |     | Podia              | 1     | Diabetes Neuro Manif Type Ii               |                             |             |     |                            | TEDN   | 104    |
| 191         | -116            | 07/08/2013                     |                | Dx        | 73394       |     | Podia              | 2     | Stress Fracture The Metatarsals            |                             |             |     |                            | TEDN   | 104    |
| 192         | -116            | 07/08/2013                     |                | Px        | 99213       |     | Podia              | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                            | TEDN   | 104    |
| 193         | -105            | 07/19/2013                     |                | Dx        | 7295        |     | Fp                 | 1     | Pain In Limb                               |                             |             |     |                            | TEDN   | 106    |
| 194         | -105            | 07/19/2013                     |                | Dx        | 78831       |     | Fp                 | 2     | Urge Incontinence                          |                             |             |     |                            | TEDN   | 106    |
| 195         | -105            | 07/19/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                            | TEDN   | 106    |
| 196         | -105            | 07/19/2013                     |                | Rx        | 00009519102 |     |                    |       |                                            | Detrol La                   | 30          | 30  | Capsule, SR 24 Hr          | PDTS   | 105    |
| 197         | -95             | 07/29/2013                     |                | Rx        | 00071015823 |     |                    |       |                                            | Lipitor                     | 90          | 90  | Tablet                     | PDTS   | 107    |
| 198         | -91             | 08/02/2013                     |                | Dx        | 5990        |     | Pa                 | 1     | Urinary Tract Infection Unspec             |                             |             |     |                            | TEDN   | 110    |
| 199         | -91             | 08/02/2013                     |                | Dx        | 7245        |     | Pa                 | 2     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 110    |
| 200         | -91             | 08/02/2013                     |                | Px        | 99284       |     | Pa                 | 1     | Emergency Department Visit High/Urgent Se  |                             |             |     |                            | TEDN   | 110    |
| 201         | -91             | 08/02/2013                     |                | Dx        | 7245        |     | Facility           | 1     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 111    |
| 202         | -91             | 08/02/2013                     |                | Dx        | 5990        |     | Facility           | 2     | Urinary Tract Infection Unspec             |                             |             |     |                            | TEDN   | 111    |
| 203         | -91             | 08/02/2013                     |                | Dx        | 412         |     | Facility           | 3     | Old Myocardial Infarction                  |                             |             |     |                            | TEDN   | 111    |
| 204         | -91             | 08/02/2013                     |                | Dx        | 41401       |     | Facility           | 4     | Atheroscler Native Coronary Art            |                             |             |     |                            | TEDN   | 111    |
| 205         | -91             | 08/02/2013                     |                | Dx        | 25000       |     | Facility           | 5     | Diabetes Uncompl Type Ii                   |                             |             |     |                            | TEDN   | 111    |
| 206         | -91             | 08/02/2013                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension         |                             |             |     |                            | TEDN   | 111    |
| 207         | -91             | 08/02/2013                     |                | Px        | 81001       |     | Facility           | 1     | Urnlis Dip Stick/Tablet Reagent Auto Micro |                             |             |     |                            | TEDN   | 111    |
| 208         | -91             | 08/02/2013                     |                | Px        | 87086       |     | Facility           | 1     | Culture Bacterial Quanttative Colony Coun  |                             |             |     |                            | TEDN   | 112    |
| 209         | -91             | 08/02/2013                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor   |                             |             |     |                            | TEDN   | 113    |
| 210         | -91             | 08/02/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever  |                             |             |     |                            | TEDN   | 114    |
| 211         | -91             | 08/02/2013                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog               |                             |             |     |                            | TEDN   | 115    |
| 212         | -91             | 08/02/2013                     |                | Rx        | 53746027205 |     |                    |       |                                            | Sulfamethoxazole-Trimethopr | 7           | 14  | Tablet                     | PDTS   | 108    |
| 213         | -91             | 08/02/2013                     |                | Rx        | 00406035705 |     |                    |       |                                            | Hydrocodone-Acetaminophen   | 2           | 14  | Tablet                     | PDTS   | 109    |
| 214         | -86             | 08/07/2013                     |                | Dx        | 7245        |     | Fp                 | 1     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 117    |
| 215         | -86             | 08/07/2013                     |                | Dx        | 5950        |     | Fp                 | 2     | Acute Cystitis                             |                             |             |     |                            | TEDN   | 117    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|----------------------------|--------|--------|
| 216         | -86             | 08/07/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 117    |
| 217         | -86             | 08/07/2013                     |                | Rx        | 63481068706 |     |                    |       |                                           | Lidoderm                   | 30          | 30  | Adhesive Patch, Medicated  | PDTS   | 116    |
| 218         | -84             | 08/09/2013                     |                | Rx        | 60505260401 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 118    |
| 219         | -84             | 08/09/2013                     |                | Rx        | 63653117105 |     |                    |       |                                           | Plavix                     | 90          | 90  | Tablet                     | PDTS   | 119    |
| 220         | -84             | 08/09/2013                     |                | Rx        | 00172531260 |     |                    |       |                                           | Ciprofloxacin Hcl          | 10          | 20  | Tablet                     | PDTS   | 120    |
| 221         | -79             | 08/14/2013                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)              | PDTS   | 121    |
| 222         | -77             | 08/16/2013                     |                | Dx        | 7242        |     | Medic              | 1     | Lumbago                                   |                            |             |     |                            | TEDN   | 122    |
| 223         | -77             | 08/16/2013                     |                | Px        | L0631       |     | Medic              | 1     | Lso Sag-Coro Rigid Frame Pre              |                            |             |     |                            | TEDN   | 122    |
| 224         | -77             | 08/16/2013                     |                | Dx        | 71947       |     | Grppract           | 1     | Pain In Joint Ankle/Foot                  |                            |             |     |                            | TEDN   | 123    |
| 225         | -77             | 08/16/2013                     |                | Dx        | 72981       |     | Grppract           | 2     | Swelling Limb                             |                            |             |     |                            | TEDN   | 123    |
| 226         | -77             | 08/16/2013                     |                | Dx        | 72673       |     | Grppract           | 3     | Calcaneal Spur                            |                            |             |     |                            | TEDN   | 123    |
| 227         | -77             | 08/16/2013                     |                | Px        | 73630       |     | Grppract           | 1     | Radex Foot Complete Minimum 3 Views       |                            |             |     |                            | TEDN   | 123    |
| 228         | -74             | 08/19/2013                     |                | Dx        | 71944       |     | Ortho              | 1     | Pain In Joint Hand                        |                            |             |     |                            | TEDN   | 125    |
| 229         | -74             | 08/19/2013                     |                | Px        | 99214       |     | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                            | TEDN   | 125    |
| 230         | -74             | 08/19/2013                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 10          | 40  | Tablet                     | PDTS   | 124    |
| 231         | -53             | 09/09/2013                     |                | Dx        | 25060       |     | Podia              | 1     | Diabetes Neuro Manif Type Ii              |                            |             |     |                            | TEDN   | 126    |
| 232         | -53             | 09/09/2013                     |                | Dx        | 3560        |     | Podia              | 2     | Hereditary Peripheral Neuropathy          |                            |             |     |                            | TEDN   | 126    |
| 233         | -53             | 09/09/2013                     |                | Dx        | 7030        |     | Podia              | 3     | Ingrowing Nail                            |                            |             |     |                            | TEDN   | 126    |
| 234         | -53             | 09/09/2013                     |                | Dx        | 1101        |     | Podia              | 4     | Dermatophytosis Nail                      |                            |             |     |                            | TEDN   | 126    |
| 235         | -53             | 09/09/2013                     |                | Dx        | 73037       |     | Podia              | 5     | Periostitis Ankle/Foot                    |                            |             |     |                            | TEDN   | 126    |
| 236         | -53             | 09/09/2013                     |                | Px        | 11721       |     | Podia              | 1     | Debridement Nail Any Method 6/>           |                            |             |     |                            | TEDN   | 126    |
| 237         | -51             | 09/11/2013                     |                | Dx        | 71534       |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                            |             |     |                            | TEDN   | 127    |
| 238         | -51             | 09/11/2013                     |                | Px        | 99212       |     | Ortho              | 1     | Office Outpatient Visit 10 Minutes        |                            |             |     |                            | TEDN   | 127    |
| 239         | -50             | 09/12/2013                     |                | Rx        | 00071101468 |     |                    |       |                                           | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 128    |
| 240         | -44             | 09/18/2013                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl              | 90          | 90  | Tablet                     | PDTS   | 129    |
| 241         | -44             | 09/18/2013                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl             | 90          | 360 | Tablet                     | PDTS   | 130    |
| 242         | -44             | 09/18/2013                     |                | Rx        | 60505260401 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 131    |
| 243         | -42             | 09/20/2013                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr            | PDTS   | 132    |
| 244         | -42             | 09/20/2013                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 133    |
| 245         | -38             | 09/24/2013                     |                | Dx        | V7281       |     | Facility           | 1     | Preop Cardiovascular Examination          |                            |             |     |                            | TEDN   | 134    |
| 246         | -38             | 09/24/2013                     |                | Dx        | 71594       |     | Facility           | 2     | Osteoarthritis Unsp Hand                  |                            |             |     |                            | TEDN   | 134    |
| 247         | -38             | 09/24/2013                     |                | Dx        | 42789       |     | Facility           | 3     | Other Cardiac Dysrhythmias                |                            |             |     |                            | TEDN   | 134    |
| 248         | -38             | 09/24/2013                     |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                            |             |     |                            | TEDN   | 134    |
| 249         | -31             | 10/01/2013                     |                | Dx        | 71534       |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                            |             |     |                            | TEDN   | 136    |
| 250         | -31             | 10/01/2013                     |                | Px        | 25310       |     | Ortho              | 1     | Tdn Trnsplj/Tr Flxr/Xtnsr F/Arm&/Wrst 1 E |                            |             |     |                            | TEDN   | 136    |
| 251         | -31             | 10/01/2013                     |                | Px        | 25447       |     | Ortho              | 1     | Arthrp Interpos Intercarpal/Metacarpal Jo |                            |             |     |                            | TEDN   | 137    |
| 252         | -31             | 10/01/2013                     |                | Dx        | 71694       |     | Grppract           | 1     | Uns Arthopathy Hand                       |                            |             |     |                            | TEDN   | 138    |
| 253         | -31             | 10/01/2013                     |                | Dx        | 412         |     | Grppract           | 2     | Old Myocardial Infarction                 |                            |             |     |                            | TEDN   | 138    |
| 254         | -31             | 10/01/2013                     |                | Dx        | 33818       |     | Grppract           | 3     | Other Acute Postoperative Pain            |                            |             |     |                            | TEDN   | 138    |
| 255         | -31             | 10/01/2013                     |                | Px        | 01830       |     | Grppract           | 1     | Anes Arthrs/Endscpy Dstl Radius Ulna/Wris |                            |             |     |                            | TEDN   | 138    |
| 256         | -31             | 10/01/2013                     |                | Px        | 64417       |     | Grppract           | 1     | Injection Anesthetic Agent Axillary Nerve |                            |             |     |                            | TEDN   | 139    |
| 257         | -31             | 10/01/2013                     |                | Dx        | 71594       |     | Facility           | 1     | Osteoarthritis Unsp Hand                  |                            |             |     |                            | TEDN   | 140    |
| 258         | -31             | 10/01/2013                     |                | Px        | 25310       |     | Facility           | 1     | Tdn Trnsplj/Tr Flxr/Xtnsr F/Arm&/Wrst 1 E |                            |             |     |                            | TEDN   | 140    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 259         | -31             | 10/01/2013                     |                | Px        | 25447       |      | Facility           | 1     | Arthrp Interpos Intercarpal/Metacarpal Jo |                        |             |     |                  | TEDN   | 141    |
| 260         | -31             | 10/01/2013                     |                | Rx        | 00378611201 |      |                    |       |                                           | Oxycodone Hcl          | 4           | 65  | Tablet           | PDTS   | 135    |
| 261         | -30             | 10/02/2013                     |                | Rx        | 67877017030 |      |                    |       |                                           | Ondansetron Hcl        | 10          | 10  | Tablet           | PDTS   | 142    |
| 262         | -19             | 10/13/2013                     |                | Dx        | 78909       |      | Ambul              | 1     | Abdominal Pain Other Site                 |                        |             |     |                  | TEDN   | 146    |
| 263         | -19             | 10/13/2013                     |                | Dx        | 78652       |      | Ambul              | 2     | Painful Respiration                       |                        |             |     |                  | TEDN   | 146    |
| 264         | -19             | 10/13/2013                     |                | Dx        | 5362        |      | Ambul              | 3     | Persistent Vomiting                       |                        |             |     |                  | TEDN   | 146    |
| 265         | -19             | 10/13/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 146    |
| 266         | -19             | 10/13/2013                     |                | Px        | A0429       |      | Ambul              | 1     | Bls-Emergency                             |                        |             |     |                  | TEDN   | 147    |
| 267         | -19             | 10/13/2013                     |                | Dx        | 42731       |      | Grpract            | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 148    |
| 268         | -19             | 10/13/2013                     |                | Dx        | 72888       |      | Grpract            | 2     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 148    |
| 269         | -19             | 10/13/2013                     |                | Px        | 36556       |      | Grpract            | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 148    |
| 270         | -19             | 10/13/2013                     |                | Px        | 99291       |      | Grpract            | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 149    |
| 271         | -19             | 10/13/2013                     |                | Px        | 99292       |      | Grpract            | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 150    |
| 272         | -19             | 10/13/2013                     |                | Px        | 71010       |      | Grpract            | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 151    |
| 273         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 42731       |      |                    | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 153    |
| 274         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 72888       |      |                    | 2     | Rhabdomyolysis                            |                        |             |     |                  | TEDI   | 153    |
| 275         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 78550       |      |                    | 3     | Shock Unspecified                         |                        |             |     |                  | TEDI   | 153    |
| 276         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 3572        |      |                    | 4     | Polyneuropathy In Diabetes                |                        |             |     |                  | TEDI   | 153    |
| 277         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 27651       |      |                    | 5     | Dehydration                               |                        |             |     |                  | TEDI   | 153    |
| 278         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 2752        |      |                    | 6     | Disorders Magnesium Metabolism            |                        |             |     |                  | TEDI   | 153    |
| 279         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 25060       |      |                    | 7     | Diabetes Neuro Manif Type II              |                        |             |     |                  | TEDI   | 153    |
| 280         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 5589        |      |                    | 8     | Oth Noninfectious Gastroenteritis         |                        |             |     |                  | TEDI   | 153    |
| 281         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 41401       |      |                    | 9     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDI   | 153    |
| 282         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 4019        |      |                    | 10    | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 153    |
| 283         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 78791       |      |                    | 11    | Diarrhea                                  |                        |             |     |                  | TEDI   | 153    |
| 284         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 2724        |      |                    | 12    | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDI   | 153    |
| 285         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 3893        |      |                    | 1     | Venous Cath Other Spec                    |                        |             |     |                  | TEDI   | 153    |
| 286         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9383        |      |                    | 2     | Occupational Therapy                      |                        |             |     |                  | TEDI   | 153    |
| 287         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9919        |      |                    | 3     | Injection Of Anticoagulant                |                        |             |     |                  | TEDI   | 153    |
| 288         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9952        |      |                    | 4     | Influenza Vaccination                     |                        |             |     |                  | TEDI   | 153    |
| 289         | -19             | 10/13/2013                     |                | Dx        | 42731       | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 143    |
| 290         | -19             | 10/13/2013                     |                | Dx        | 4293        | Inpt | Cardvasc           | 2     | Cardiomegaly                              |                        |             |     |                  | TEDN   | 143    |
| 291         | -19             | 10/13/2013                     |                | Dx        | 72888       | Inpt | Cardvasc           | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 143    |
| 292         | -19             | 10/13/2013                     |                | Px        | 93010       | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 143    |
| 293         | -19             | 10/13/2013                     |                | Px        | 93010       | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 144    |
| 294         | -19             | 10/13/2013                     |                | Dx        | 78650       | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 145    |
| 295         | -19             | 10/13/2013                     |                | Dx        | 42731       | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 145    |
| 296         | -19             | 10/13/2013                     |                | Dx        | 72888       | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 145    |
| 297         | -19             | 10/13/2013                     |                | Dx        | 78550       | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 145    |
| 298         | -19             | 10/13/2013                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 145    |
| 300         | -18             | 10/14/2013                     |                | Dx        | 42731       | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 154    |
| 301         | -18             | 10/14/2013                     |                | Dx        | 25002       | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 154    |
| 302         | -18             | 10/14/2013                     |                | Dx        | 41401       | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 154    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 303         | -18             | 10/14/2013                     |                | Dx        | 4011  | Inpt | Cardvasc           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 154    |
| 304         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 154    |
| 305         | -18             | 10/14/2013                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 155    |
| 306         | -18             | 10/14/2013                     |                | Dx        | 78650 | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 156    |
| 307         | -18             | 10/14/2013                     |                | Dx        | 42731 | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 156    |
| 308         | -18             | 10/14/2013                     |                | Dx        | 72888 | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 156    |
| 309         | -18             | 10/14/2013                     |                | Dx        | 78550 | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 156    |
| 310         | -18             | 10/14/2013                     |                | Px        | 99233 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 156    |
| 311         | -18             | 10/14/2013                     |                | Dx        | 28860 | Inpt | Intmed             | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 157    |
| 312         | -18             | 10/14/2013                     |                | Px        | 99223 | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 157    |
| 313         | -18             | 10/14/2013                     |                | Dx        | 7905  | Inpt | Radio              | 1     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 158    |
| 314         | -18             | 10/14/2013                     |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 158    |
| 315         | -18             | 10/14/2013                     |                | Dx        | 0389  | Inpt | Grppract           | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 159    |
| 316         | -18             | 10/14/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 159    |
| 317         | -18             | 10/14/2013                     |                | Dx        | 99592 | Inpt | Grppract           | 3     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 159    |
| 318         | -18             | 10/14/2013                     |                | Dx        | 4271  | Inpt | Grppract           | 4     | Paroxysmal Ventricular Tachycardia        |                        |             |     |                  | TEDN   | 159    |
| 319         | -18             | 10/14/2013                     |                | Px        | 99292 | Inpt | Grppract           | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 159    |
| 320         | -18             | 10/14/2013                     |                | Px        | 99291 | Inpt | Grppract           | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 160    |
| 321         | -18             | 10/14/2013                     |                | Px        | 71260 | Inpt | Grppract           | 1     | Ct Thorax W/Contrast Material             |                        |             |     |                  | TEDN   | 161    |
| 322         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 162    |
| 323         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 163    |
| 324         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 164    |
| 325         | -17             | 10/15/2013                     |                | Dx        | 25002 | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 164    |
| 326         | -17             | 10/15/2013                     |                | Dx        | 41401 | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 164    |
| 327         | -17             | 10/15/2013                     |                | Dx        | 4011  | Inpt | Cardvasc           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 164    |
| 328         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 164    |
| 329         | -17             | 10/15/2013                     |                | Dx        | 78650 | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 165    |
| 330         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 165    |
| 331         | -17             | 10/15/2013                     |                | Dx        | 72888 | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 165    |
| 332         | -17             | 10/15/2013                     |                | Dx        | 78550 | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 165    |
| 333         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 165    |
| 334         | -17             | 10/15/2013                     |                | Dx        | 28860 | Inpt | Intmed             | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 166    |
| 335         | -17             | 10/15/2013                     |                | Px        | 99233 | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 166    |
| 336         | -17             | 10/15/2013                     |                | Dx        | 0389  | Inpt | Grppract           | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 167    |
| 337         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 167    |
| 338         | -17             | 10/15/2013                     |                | Dx        | 99592 | Inpt | Grppract           | 3     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 167    |
| 339         | -17             | 10/15/2013                     |                | Dx        | 4271  | Inpt | Grppract           | 4     | Paroxysmal Ventricular Tachycardia        |                        |             |     |                  | TEDN   | 167    |
| 340         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 167    |
| 341         | -17             | 10/15/2013                     |                | Px        | 99231 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 168    |
| 342         | -17             | 10/15/2013                     |                | Px        | 99231 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 169    |
| 343         | -16             | 10/16/2013                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 170    |
| 344         | -16             | 10/16/2013                     |                | Dx        | 25002 | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 170    |
| 345         | -16             | 10/16/2013                     |                | Dx        | 41401 | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 170    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|------|--------------------|--------|-------------------------------------------|------------------------|-------------|-----|-----------------------------|--------|--------|
| 346         | -16             | 10/16/2013                     |                | Dx        | 4011             | Inpt | Cardvasc           | 4      | Benign Essential Hypertension             |                        |             |     |                             | TEDN   | 170    |
| 347         | -16             | 10/16/2013                     |                | Px        | 99232            | Inpt | Cardvasc           | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 170    |
| 348         | -16             | 10/16/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 171    |
| 349         | -16             | 10/16/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 171    |
| 350         | -16             | 10/16/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 171    |
| 351         | -16             | 10/16/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 171    |
| 352         | -16             | 10/16/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 171    |
| 353         | -16             | 10/16/2013                     |                | Dx        | 28860            | Inpt | Intmed             | 1      | Leukocytosis Unspecified                  |                        |             |     |                             | TEDN   | 172    |
| 354         | -16             | 10/16/2013                     |                | Px        | 99233            | Inpt | Intmed             | 1      | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                             | TEDN   | 172    |
| 355         | -15             | 10/17/2013                     |                | Dx        | 42731            | Inpt | Cardvasc           | 1      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 173    |
| 356         | -15             | 10/17/2013                     |                | Dx        | 25002            | Inpt | Cardvasc           | 2      | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                             | TEDN   | 173    |
| 357         | -15             | 10/17/2013                     |                | Dx        | 41401            | Inpt | Cardvasc           | 3      | Atheroscler Native Coronary Art           |                        |             |     |                             | TEDN   | 173    |
| 358         | -15             | 10/17/2013                     |                | Dx        | 4011             | Inpt | Cardvasc           | 4      | Benign Essential Hypertension             |                        |             |     |                             | TEDN   | 173    |
| 359         | -15             | 10/17/2013                     |                | Px        | 99232            | Inpt | Cardvasc           | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 173    |
| 360         | -15             | 10/17/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 174    |
| 361         | -15             | 10/17/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 174    |
| 362         | -15             | 10/17/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 174    |
| 363         | -15             | 10/17/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 174    |
| 364         | -15             | 10/17/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 174    |
| 365         | -15             | 10/17/2013                     |                | Dx        | 28860            | Inpt | Intmed             | 1      | Leukocytosis Unspecified                  |                        |             |     |                             | TEDN   | 175    |
| 366         | -15             | 10/17/2013                     |                | Px        | 99232            | Inpt | Intmed             | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 175    |
| 367         | -15             | 10/17/2013                     |                | Dx        | 78605            | Inpt | Radio              | 1      | Shortness Breath                          |                        |             |     |                             | TEDN   | 176    |
| 368         | -15             | 10/17/2013                     |                | Dx        | 78060            | Inpt | Radio              | 2      | Fever Unspecified                         |                        |             |     |                             | TEDN   | 176    |
| 369         | -15             | 10/17/2013                     |                | Px        | 71020            | Inpt | Radio              | 1      | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                             | TEDN   | 176    |
| 375         | -14             | 10/18/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 177    |
| 376         | -14             | 10/18/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 177    |
| 377         | -14             | 10/18/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 177    |
| 378         | -14             | 10/18/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 177    |
| 379         | -14             | 10/18/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 177    |
| 370         | -14             | 10/18/2013                     |                | Dx        | 7812             |      | Ambul              | 1      | Abnormality Of Gait                       |                        |             |     |                             | TEDN   | 178    |
| 371         | -14             | 10/18/2013                     |                | Dx        | V4984            |      | Ambul              | 2      | Bed Confinement Status                    |                        |             |     |                             | TEDN   | 178    |
| 372         | -14             | 10/18/2013                     |                | Dx        | 7993             |      | Ambul              | 3      | Debility Unspecified                      |                        |             |     |                             | TEDN   | 178    |
| 373         | -14             | 10/18/2013                     |                | Px        | A0425            |      | Ambul              | 1      | Ground Mileage                            |                        |             |     |                             | TEDN   | 178    |
| 374         | -14             | 10/18/2013                     |                | Px        | A0428            |      | Ambul              | 1      | Bls                                       |                        |             |     |                             | TEDN   | 179    |
| 380         | -9              | 10/23/2013                     |                | Dx        | 7295             |      | Fp                 | 1      | Pain In Limb                              |                        |             |     |                             | TEDN   | 180    |
| 381         | -9              | 10/23/2013                     |                | Px        | 99309            |      | Fp                 | 1      | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                             | TEDN   | 180    |
| 382         | 0               | 11/01/2013                     |                | Rx        | 00378668910      |      |                    |        |                                           | Pantoprazole Sodium    | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 181    |
| 383         | 0               | 11/01/2013                     |                | Rx        | 45963053830      |      |                    |        |                                           | Ondansetron Hcl        | 8           | 30  | Tablet                      | PDTS   | 182    |
| 384         | 0               | 11/01/2013                     |                | Rx        | 68382006401      |      |                    |        |                                           | Warfarin Sodium        | 30          | 30  | Tablet                      | PDTS   | 183    |
| 385         | 0               | 11/01/2013                     |                | Rx        | 64980015701      |      |                    |        |                                           | Vitamin D2             | 28          | 4   | Capsule (Hard, Soft, Etc.)  | PDTS   | 184    |
| 386         | 0               | 11/01/2013                     |                | Rx        | 00310075290      |      |                    |        |                                           | Crestor                | 30          | 30  | Tablet                      | PDTS   | 185    |
| 387         | 0               | 11/01/2013                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |        |                                           | INDEX STUDY DRUG       | 30          |     | INITIAL FILL                | PDTS   | 186    |
| 388         | 3               | 11/04/2013                     |                | Dx        | 42731            |      | Grppract           | 1      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 187    |

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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge<br>Date | Code Type | Code             | POS | Provider<br>Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description    | Days Supply | QTY | Drug Formulation            | Source | Record |
|-------------|-----------------|--------------------------------|-------------------|-----------|------------------|-----|-----------------------|-------|-------------------------------------------|---------------------------|-------------|-----|-----------------------------|--------|--------|
| 389         | 3               | 11/04/2013                     |                   | Px        | 99213            |     | Grppract              | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                             | TEDN   | 187    |
| 390         | 5               | 11/06/2013                     |                   | Dx        | 71534            |     | Ortho                 | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 188    |
| 391         | 5               | 11/06/2013                     |                   | Px        | 73130            |     | Ortho                 | 1     | Radex Hand Minimum 3 Views                |                           |             |     |                             | TEDN   | 188    |
| 392         | 5               | 11/06/2013                     |                   | Dx        | 7812             |     | Grppract              | 1     | Abnormality Of Gait                       |                           |             |     |                             | TEDN   | 189    |
| 393         | 5               | 11/06/2013                     |                   | Px        | 97001            |     | Grppract              | 1     | Physical Therapy Evaluation               |                           |             |     |                             | TEDN   | 189    |
| 394         | 5               | 11/06/2013                     |                   | Px        | 97110            |     | Grppract              | 1     | Therapeutic Px 1/> Areas Each 15 Min Exer |                           |             |     |                             | TEDN   | 190    |
| 395         | 5               | 11/06/2013                     |                   | Px        | 97530            |     | Grppract              | 1     | Ther Actv Dir Pt Contact By Provider Each |                           |             |     |                             | TEDN   | 191    |
| 396         | 18              | 11/19/2013                     |                   | Rx        | 55111012705      |     |                       |       |                                           | Ciprofloxacin Hcl         | 7           | 14  | Tablet                      | PDTS   | 192    |
| 397         | 20              | 11/21/2013                     |                   | Dx        | 71534            |     | Ortho                 | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 196    |
| 398         | 20              | 11/21/2013                     |                   | Px        | 73110            |     | Ortho                 | 1     | Radex Wrist Complete Minimum 3 Views      |                           |             |     |                             | TEDN   | 196    |
| 399         | 20              | 11/21/2013                     |                   | Dx        | 71534            |     | Grppract              | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 197    |
| 400         | 20              | 11/21/2013                     |                   | Px        | L3908            |     | Grppract              | 1     | Wrist Cock-Up Non-Molded                  |                           |             |     |                             | TEDN   | 197    |
| 401         | 20              | 11/21/2013                     |                   | Rx        | 59762444002      |     |                       |       |                                           | Methylprednisolone        | 6           | 21  | Tablet, Dose Pack           | PDTS   | 193    |
| 402         | 20              | 11/21/2013                     |                   | Rx        | 00071101468      |     |                       |       |                                           | Lyrica                    | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 194    |
| 403         | 20              | 11/21/2013                     |                   | Rx        | 00406051205      |     |                       |       |                                           | Oxycodone-Acetaminophen   | 3           | 40  | Tablet                      | PDTS   | 195    |
| 404         | 29              | 11/30/2013                     |                   | Rx        | 00378668910      |     |                       |       |                                           | Pantoprazole Sodium       | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 198    |
| 405         | 29              | 11/30/2013                     |                   | Rx        | INDEX STUDY DRUG |     |                       |       |                                           | INDEX STUDY DRUG          | 30          |     | REFILL                      | PDTS   | 199    |
| 406         | 29              | 11/30/2013                     |                   | Rx        | 68382006401      |     |                       |       |                                           | Warfarin Sodium           | 30          | 30  | Tablet                      | PDTS   | 200    |
| 407         | 29              | 11/30/2013                     |                   | Rx        | 00310075290      |     |                       |       |                                           | Crestor                   | 30          | 30  | Tablet                      | PDTS   | 201    |
| 408         | 46              | 12/17/2013                     |                   | Dx        | 41401            |     | Cardvasc              | 1     | Atheroscler Native Coronary Art           |                           |             |     |                             | TEDN   | 204    |
| 409         | 46              | 12/17/2013                     |                   | Dx        | 4011             |     | Cardvasc              | 2     | Benign Essential Hypertension             |                           |             |     |                             | TEDN   | 204    |
| 410         | 46              | 12/17/2013                     |                   | Dx        | 2722             |     | Cardvasc              | 3     | Mixed Hyperlipidemia                      |                           |             |     |                             | TEDN   | 204    |
| 411         | 46              | 12/17/2013                     |                   | Dx        | 25000            |     | Cardvasc              | 4     | Diabetes Uncompl Type Ii                  |                           |             |     |                             | TEDN   | 204    |
| 412         | 46              | 12/17/2013                     |                   | Px        | 99214            |     | Cardvasc              | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                             | TEDN   | 204    |
| 413         | 46              | 12/17/2013                     |                   | Rx        | 0                |     |                       |       |                                           | Compounded Medication     | 6           | 360 |                             | PDTS   | 202    |
| 414         | 46              | 12/17/2013                     |                   | Rx        | 00603646832      |     |                       |       |                                           | Zolpidem Tartrate         | 30          | 30  | Tablet                      | PDTS   | 203    |
| 415         | 52              | 12/23/2013                     |                   | Dx        | 25060            |     | Podia                 | 1     | Diabetes Neuro Manif Type Ii              |                           |             |     |                             | TEDN   | 205    |
| 416         | 52              | 12/23/2013                     |                   | Dx        | 3560             |     | Podia                 | 2     | Hereditary Peripheral Neuropathy          |                           |             |     |                             | TEDN   | 205    |
| 417         | 52              | 12/23/2013                     |                   | Dx        | 7030             |     | Podia                 | 3     | Ingrowing Nail                            |                           |             |     |                             | TEDN   | 205    |
| 418         | 52              | 12/23/2013                     |                   | Dx        | 1101             |     | Podia                 | 4     | Dermatophytosis Nail                      |                           |             |     |                             | TEDN   | 205    |
| 419         | 52              | 12/23/2013                     |                   | Dx        | 73037            |     | Podia                 | 5     | Periostitis Ankle/Foot                    |                           |             |     |                             | TEDN   | 205    |
| 420         | 52              | 12/23/2013                     |                   | Px        | 11721            |     | Podia                 | 1     | Debridement Nail Any Method 6/>           |                           |             |     |                             | TEDN   | 205    |
| 421         | 55              | 12/26/2013                     |                   | Dx        | 92411            |     | Ortho                 | 1     | Contusion Of Knee                         |                           |             |     |                             | TEDN   | 207    |
| 422         | 55              | 12/26/2013                     |                   | Px        | 99214            |     | Ortho                 | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                             | TEDN   | 207    |
| 423         | 55              | 12/26/2013                     |                   | Dx        | 71946            |     | Grppract              | 1     | Pain In Joint Lower Leg                   |                           |             |     |                             | TEDN   | 208    |
| 424         | 55              | 12/26/2013                     |                   | Dx        | V4365            |     | Grppract              | 2     | Knee Joint Replacement                    |                           |             |     |                             | TEDN   | 208    |
| 425         | 55              | 12/26/2013                     |                   | Px        | 73562            |     | Grppract              | 1     | Radiologic Examination Knee 3 Views       |                           |             |     |                             | TEDN   | 208    |
| 426         | 55              | 12/26/2013                     |                   | Rx        | 00603389028      |     |                       |       |                                           | Hydrocodone-Acetaminophen | 10          | 40  | Tablet                      | PDTS   | 206    |
| 427         | 59              | 12/30/2013                     |                   | Rx        | 00071101468      |     |                       |       |                                           | Lyrica                    | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 209    |
| 428         | 61              | 01/01/2014                     |                   | Dx        | 7245             |     | Pa                    | 1     | Backache Unspecified                      |                           |             |     |                             | TEDN   | 214    |
| 429         | 61              | 01/01/2014                     |                   | Px        | 99283            |     | Pa                    | 1     | Emergency Department Visit Moderate Sever |                           |             |     |                             | TEDN   | 214    |
| 430         | 61              | 01/01/2014                     |                   | Dx        | 33819            |     | Facility              | 1     | Other Acute Pain                          |                           |             |     |                             | TEDN   | 215    |
| 431         | 61              | 01/01/2014                     |                   | Dx        | 7245             |     | Facility              | 2     | Backache Unspecified                      |                           |             |     |                             | TEDN   | 215    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|-----------------------------|--------|--------|
| 432         | 61              | 01/01/2014                     |                | Dx        | 25000       |     | Facility           | 3     | Diabetes Uncompl Type II                  |                            |             |     |                             | TEDN   | 215    |
| 433         | 61              | 01/01/2014                     |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                            |             |     |                             | TEDN   | 215    |
| 434         | 61              | 01/01/2014                     |                | Dx        | 41400       |     | Facility           | 5     | Coronary Atheroscler Uns Vessel           |                            |             |     |                             | TEDN   | 215    |
| 435         | 61              | 01/01/2014                     |                | Dx        | 412         |     | Facility           | 6     | Old Myocardial Infarction                 |                            |             |     |                             | TEDN   | 215    |
| 436         | 61              | 01/01/2014                     |                | Dx        | 42731       |     | Facility           | 7     | Atrial Fibrillation                       |                            |             |     |                             | TEDN   | 215    |
| 437         | 61              | 01/01/2014                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                            |             |     |                             | TEDN   | 215    |
| 438         | 61              | 01/01/2014                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor  |                            |             |     |                             | TEDN   | 216    |
| 439         | 61              | 01/01/2014                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                            |             |     |                             | TEDN   | 217    |
| 440         | 61              | 01/01/2014                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog              |                            |             |     |                             | TEDN   | 218    |
| 441         | 61              | 01/01/2014                     |                | Rx        | 00054001925 |     |                    |       |                                           | Prednisone                 | 4           | 4   | Tablet                      | PDTS   | 210    |
| 442         | 61              | 01/01/2014                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 4           | 14  | Tablet                      | PDTS   | 211    |
| 443         | 61              | 01/01/2014                     |                | Rx        | 59746021110 |     |                    |       |                                           | Cyclobenzaprine Hcl        | 6           | 20  | Tablet                      | PDTS   | 212    |
| 444         | 61              | 01/01/2014                     |                | Rx        | 45963053830 |     |                    |       |                                           | Ondansetron Hcl            | 3           | 10  | Tablet                      | PDTS   | 213    |
| 445         | 62              | 01/02/2014                     |                | Rx        | 00378668910 |     |                    |       |                                           | Pantoprazole Sodium        | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 219    |
| 446         | 62              | 01/02/2014                     |                | Rx        | 00310075290 |     |                    |       |                                           | Crestor                    | 30          | 30  | Tablet                      | PDTS   | 220    |
| 447         | 69              | 01/09/2014                     |                | Dx        | 42769       |     | Facility           | 1     | Oth Premature Beats                       |                            |             |     |                             | TEDN   | 221    |
| 448         | 69              | 01/09/2014                     |                | Dx        | 42761       |     | Facility           | 2     | Supraventricular Premature Beats          |                            |             |     |                             | TEDN   | 221    |
| 449         | 69              | 01/09/2014                     |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                            |             |     |                             | TEDN   | 221    |
| 450         | 69              | 01/09/2014                     |                | Px        | 93225       |     | Facility           | 1     | Xtrnl Ecg < 48 Hr Recording               |                            |             |     |                             | TEDN   | 221    |
| 451         | 69              | 01/09/2014                     |                | Px        | 93226       |     | Facility           | 1     | External Ecg Scanning Analysis Report     |                            |             |     |                             | TEDN   | 222    |
| 452         | 76              | 01/16/2014                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                             | TEDN   | 223    |
| 453         | 76              | 01/16/2014                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                            |             |     |                             | TEDN   | 223    |
| 454         | 76              | 01/16/2014                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                            |             |     |                             | TEDN   | 223    |
| 455         | 76              | 01/16/2014                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type II                  |                            |             |     |                             | TEDN   | 223    |
| 456         | 76              | 01/16/2014                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                             | TEDN   | 223    |
| 457         | 87              | 01/27/2014                     |                | Dx        | 7295        |     | Grpract            | 1     | Pain In Limb                              |                            |             |     |                             | TEDN   | 225    |
| 458         | 87              | 01/27/2014                     |                | Px        | 99213       |     | Grpract            | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                             | TEDN   | 225    |
| 459         | 87              | 01/27/2014                     |                | Rx        | 57664037718 |     |                    |       |                                           | Tramadol Hcl               | 12          | 50  | Tablet                      | PDTS   | 224    |
| 460         | 93              | 02/02/2014                     |                | Rx        | 00071101468 |     |                    |       |                                           | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 226    |
| 461         | 101             | 02/10/2014                     |                | Rx        | 54569214000 |     |                    |       |                                           | Nitrostat                  | 30          | 100 | Tablet, Sublingual          | PDTS   | 227    |
| 462         | 101             | 02/10/2014                     |                | Rx        | 63653117105 |     |                    |       |                                           | Plavix                     | 90          | 90  | Tablet                      | PDTS   | 228    |
| 463         | 101             | 02/10/2014                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl             | 90          | 360 | Tablet                      | PDTS   | 229    |
| 464         | 101             | 02/10/2014                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr             | PDTS   | 230    |
| 465         | 101             | 02/10/2014                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.)  | PDTS   | 231    |
| 466         | 101             | 02/10/2014                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl              | 90          | 90  | Tablet                      | PDTS   | 232    |
| 467         | 102             | 02/11/2014                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                      | PDTS   | 233    |
| 468         | 102             | 02/11/2014                     |                | Rx        | 00008084181 |     |                    |       |                                           | Protonix                   | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 234    |
| 469         | 102             | 02/11/2014                     |                | Rx        | 00310075290 |     |                    |       |                                           | Crestor                    | 90          | 90  | Tablet                      | PDTS   | 235    |
| 470         | 102             | 02/11/2014                     |                | Rx        | 00009519103 |     |                    |       |                                           | Detrol La                  | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 236    |
| 471         | 125             | 03/06/2014                     |                | Dx        | 71946       |     | Ortho              | 1     | Pain In Joint Lower Leg                   |                            |             |     |                             | TEDN   | 239    |
| 472         | 125             | 03/06/2014                     |                | Px        | 99214       |     | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                             | TEDN   | 239    |
| 473         | 125             | 03/06/2014                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)               | PDTS   | 237    |
| 474         | 125             | 03/06/2014                     |                | Rx        | 00093015010 |     |                    |       |                                           | Acetaminophen-Codeine      | 15          | 90  | Tablet                      | PDTS   | 238    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 475         | 127             | 03/08/2014                     |                | Rx        | 00071101468 |      |                    |       |                                           | Lyrica                 | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 240    |
| 476         | 150             | 03/31/2014                     |                | Dx        | 25060       |      | Podia              | 1     | Diabetes Neuro Manif Type Ii              |                        |             |     |                            | TEDN   | 241    |
| 477         | 150             | 03/31/2014                     |                | Dx        | 3560        |      | Podia              | 2     | Hereditary Peripheral Neuropathy          |                        |             |     |                            | TEDN   | 241    |
| 478         | 150             | 03/31/2014                     |                | Dx        | 7030        |      | Podia              | 3     | Ingrowing Nail                            |                        |             |     |                            | TEDN   | 241    |
| 479         | 150             | 03/31/2014                     |                | Dx        | 1101        |      | Podia              | 4     | Dermatophytosis Nail                      |                        |             |     |                            | TEDN   | 241    |
| 480         | 150             | 03/31/2014                     |                | Dx        | 73037       |      | Podia              | 5     | Periostitis Ankle/Foot                    |                        |             |     |                            | TEDN   | 241    |
| 481         | 150             | 03/31/2014                     |                | Dx        | 3556        |      | Podia              | 6     | Lesion Plantar Nerve                      |                        |             |     |                            | TEDN   | 241    |
| 482         | 150             | 03/31/2014                     |                | Dx        | 73399       |      | Podia              | 7     | Other Disorders Bone/Cartilage            |                        |             |     |                            | TEDN   | 241    |
| 483         | 150             | 03/31/2014                     |                | Px        | 11721       |      | Podia              | 1     | Debridement Nail Any Method 6/>           |                        |             |     |                            | TEDN   | 241    |
| 484         | 150             | 03/31/2014                     |                | Px        | 99212       |      | Podia              | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                            | TEDN   | 242    |
| 485         | 150             | 03/31/2014                     |                | Dx        | 7823        |      | Grppract           | 1     | Edema                                     |                        |             |     |                            | TEDN   | 243    |
| 486         | 150             | 03/31/2014                     |                | Dx        | 7822        |      | Grppract           | 2     | Localized Superficial Swelling            |                        |             |     |                            | TEDN   | 243    |
| 487         | 150             | 03/31/2014                     |                | Px        | 73721       |      | Grppract           | 1     | Mri Any Jt Lower Extrem W/O Contrast Matr |                        |             |     |                            | TEDN   | 243    |
| 488         | 160             | 04/10/2014                     |                | Dx        | 7245        |      | Fp                 | 1     | Backache Unspecified                      |                        |             |     |                            | TEDN   | 244    |
| 489         | 160             | 04/10/2014                     |                | Dx        | 3572        |      | Fp                 | 2     | Polyneuropathy In Diabetes                |                        |             |     |                            | TEDN   | 244    |
| 490         | 160             | 04/10/2014                     |                | Dx        | 25000       |      | Fp                 | 3     | Diabetes Uncompl Type Ii                  |                        |             |     |                            | TEDN   | 244    |
| 491         | 160             | 04/10/2014                     |                | Dx        | 8472        |      | Fp                 | 4     | Sprain/Strain Lumbar Region               |                        |             |     |                            | TEDN   | 244    |
| 492         | 160             | 04/10/2014                     |                | Dx        | 5950        |      | Fp                 | 5     | Acute Cystitis                            |                        |             |     |                            | TEDN   | 244    |
| 493         | 160             | 04/10/2014                     |                | Px        | 81002       |      | Fp                 | 1     | Urnl's Dip Stick/Tablet Rgnt Non-Auto W/O |                        |             |     |                            | TEDN   | 244    |
| 494         | 160             | 04/10/2014                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 245    |
| 495         | 164             | 04/14/2014                     |                | Rx        | 00071101468 |      |                    |       |                                           | Lyrica                 | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 246    |
| 496         | 165             | 04/15/2014                     |                | Rx        | 57664037718 |      |                    |       |                                           | Tramadol Hcl           | 12          | 50  | Tablet                     | PDTS   | 247    |
| 497         | 178             | 04/28/2014                     |                | Dx        | 25000       |      | Fp                 | 1     | Diabetes Uncompl Type Ii                  |                        |             |     |                            | TEDN   | 250    |
| 498         | 178             | 04/28/2014                     |                | Dx        | 460         |      | Fp                 | 2     | Acute Nasopharyngitis                     |                        |             |     |                            | TEDN   | 250    |
| 499         | 178             | 04/28/2014                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 250    |
| 500         | 178             | 04/28/2014                     |                | Rx        | 57664018534 |      |                    |       |                                           | Promethazine-Codeine   | 18          | 180 | Syrup                      | PDTS   | 248    |
| 501         | 178             | 04/28/2014                     |                | Rx        | 00781506101 |      |                    |       |                                           | Amoxicillin            | 10          | 20  | Tablet                     | PDTS   | 249    |
| 502         | 193             | 05/13/2014                     |                | Dx        | 51881       |      | Gp                 | 1     | Respiratory Failure                       |                        |             |     |                            | TEDN   | 251    |
| 503         | 193             | 05/13/2014                     |                | Dx        | 0389        |      | Gp                 | 2     | Un's Septicemia                           |                        |             |     |                            | TEDN   | 251    |
| 504         | 193             | 05/13/2014                     |                | Dx        | 486         |      | Gp                 | 3     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 251    |
| 505         | 193             | 05/13/2014                     |                | Px        | 93010       |      | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                            | TEDN   | 251    |
| 506         | 193             | 05/13/2014                     |                | Px        | 99291       |      | Gp                 | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                            | TEDN   | 252    |
| 507         | 193             | 05/13/2014                     |                | Dx        | 78791       | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                            | TEDN   | 253    |
| 508         | 193             | 05/13/2014                     |                | Dx        | 51881       | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                            | TEDN   | 253    |
| 509         | 193             | 05/13/2014                     |                | Dx        | 5168        | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                            | TEDN   | 253    |
| 510         | 193             | 05/13/2014                     |                | Dx        | 486         | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 253    |
| 511         | 193             | 05/13/2014                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                            | TEDN   | 253    |
| 512         | 193             | 05/13/2014                     |                | Dx        | 486         | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 254    |
| 513         | 193             | 05/13/2014                     |                | Px        | 71010       | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                            | TEDN   | 254    |
| 514         | 193             | 05/13/2014                     |                | Dx        | 78703       | Inpt | Grppract           | 1     | Vomiting Alone                            |                        |             |     |                            | TEDN   | 255    |
| 515         | 193             | 05/13/2014                     |                | Px        | 93010       | Inpt | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                            | TEDN   | 255    |
| 516         | 194             | 05/14/2014                     |                | Dx        | 41401       | Inpt | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                        |             |     |                            | TEDN   | 256    |
| 517         | 194             | 05/14/2014                     |                | Dx        | 42731       | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 256    |



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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code  | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 518         | 194             | 05/14/2014                     |                | Dx        | 4011  | Inpt | Cardvasc           | 3     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 256    |
| 519         | 194             | 05/14/2014                     |                | Dx        | 2722  | Inpt | Cardvasc           | 4     | Mixed Hyperlipidemia                      |                        |             |     |                  | TEDN   | 256    |
| 520         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 256    |
| 521         | 194             | 05/14/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 257    |
| 522         | 194             | 05/14/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 257    |
| 523         | 194             | 05/14/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 257    |
| 524         | 194             | 05/14/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 257    |
| 525         | 194             | 05/14/2014                     |                | Px        | 99233 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 257    |
| 526         | 194             | 05/14/2014                     |                | Dx        | 486   | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 258    |
| 527         | 194             | 05/14/2014                     |                | Px        | 71250 | Inpt | Radio              | 1     | Ct Thorax W/O Contrast Material           |                        |             |     |                  | TEDN   | 258    |
| 528         | 194             | 05/14/2014                     |                | Px        | 74176 | Inpt | Radio              | 1     | Ct Abdomen & Pelvis W/O Contrast Material |                        |             |     |                  | TEDN   | 259    |
| 529         | 194             | 05/14/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 260    |
| 530         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 260    |
| 531         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 261    |
| 532         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 0389  |      |                    | 1     | Uns Septicemia                            |                        |             |     |                  | TEDI   | 266    |
| 533         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 51881 |      |                    | 2     | Respiratory Failure                       |                        |             |     |                  | TEDI   | 266    |
| 534         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 486   |      |                    | 3     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDI   | 266    |
| 535         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 5168  |      |                    | 4     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDI   | 266    |
| 536         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 42731 |      |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 266    |
| 537         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 412   |      |                    | 6     | Old Myocardial Infarction                 |                        |             |     |                  | TEDI   | 266    |
| 538         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 25000 |      |                    | 7     | Diabetes Uncompl Type II                  |                        |             |     |                  | TEDI   | 266    |
| 539         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 99591 |      |                    | 8     | Sepsis                                    |                        |             |     |                  | TEDI   | 266    |
| 540         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 53081 |      |                    | 9     | Esophageal Reflux                         |                        |             |     |                  | TEDI   | 266    |
| 541         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 4019  |      |                    | 10    | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 266    |
| 542         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 41401 |      |                    | 11    | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDI   | 266    |
| 543         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 2724  |      |                    | 12    | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDI   | 266    |
| 544         | 195             | 05/15/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 262    |
| 545         | 195             | 05/15/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 262    |
| 546         | 195             | 05/15/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 262    |
| 547         | 195             | 05/15/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 262    |
| 548         | 195             | 05/15/2014                     |                | Px        | 99232 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 262    |
| 549         | 195             | 05/15/2014                     |                | Dx        | 79902 | Inpt | Radio              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 263    |
| 550         | 195             | 05/15/2014                     |                | Dx        | 78079 | Inpt | Radio              | 2     | Other Malaise And Fatigue                 |                        |             |     |                  | TEDN   | 263    |
| 551         | 195             | 05/15/2014                     |                | Px        | 78582 | Inpt | Radio              | 1     | Pulmonary Ventilation & Perfusion Imaging |                        |             |     |                  | TEDN   | 263    |
| 552         | 195             | 05/15/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 264    |
| 553         | 195             | 05/15/2014                     |                | Px        | 99232 | Inpt | Grpprac            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 264    |
| 554         | 195             | 05/15/2014                     |                | Px        | 71010 | Inpt | Grpprac            | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 265    |
| 555         | 196             | 05/16/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 267    |
| 556         | 196             | 05/16/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 267    |
| 557         | 196             | 05/16/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 267    |
| 558         | 196             | 05/16/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 267    |
| 559         | 196             | 05/16/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 267    |
| 560         | 196             | 05/16/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 268    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|--------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 561         | 196             | 05/16/2014                     |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes    |                        |             |     |                  | TEDN   | 268    |
| 562         | 196             | 05/16/2014                     |                | Px        | 71260 | Inpt | Grppract           | 1     | Ct Thorax W/Contrast Material        |                        |             |     |                  | TEDN   | 269    |
| 563         | 197             | 05/17/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 270    |
| 564         | 197             | 05/17/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 270    |
| 565         | 197             | 05/17/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 270    |
| 566         | 197             | 05/17/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 270    |
| 567         | 197             | 05/17/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 270    |
| 568         | 198             | 05/18/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 271    |
| 569         | 198             | 05/18/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 271    |
| 570         | 198             | 05/18/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 271    |
| 571         | 198             | 05/18/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 271    |
| 572         | 198             | 05/18/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 271    |
| 573         | 199             | 05/19/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 272    |
| 574         | 199             | 05/19/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 272    |
| 575         | 199             | 05/19/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 272    |
| 576         | 199             | 05/19/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 272    |
| 577         | 199             | 05/19/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 272    |
| 578         | 199             | 05/19/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 273    |
| 579         | 199             | 05/19/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 273    |
| 580         | 199             | 05/19/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 274    |
| 581         | 200             | 05/20/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 275    |
| 582         | 200             | 05/20/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 275    |
| 583         | 200             | 05/20/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 275    |
| 584         | 200             | 05/20/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 275    |
| 585         | 200             | 05/20/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 275    |
| 586         | 200             | 05/20/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 276    |
| 587         | 200             | 05/20/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 276    |
| 588         | 200             | 05/20/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 277    |
| 589         | 201             | 05/21/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 278    |
| 590         | 201             | 05/21/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 278    |
| 591         | 201             | 05/21/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 278    |
| 592         | 201             | 05/21/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 278    |
| 593         | 201             | 05/21/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 278    |
| 594         | 201             | 05/21/2014                     |                | Dx        | 5183  | Inpt | Radio              | 1     | Pulmonary Eosinophilia               |                        |             |     |                  | TEDN   | 279    |
| 595         | 201             | 05/21/2014                     |                | Px        | 71250 | Inpt | Radio              | 1     | Ct Thorax W/O Contrast Material      |                        |             |     |                  | TEDN   | 279    |
| 596         | 201             | 05/21/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 280    |
| 597         | 201             | 05/21/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 280    |
| 598         | 201             | 05/21/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 281    |
| 607         | 202             | 05/22/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 287    |
| 608         | 202             | 05/22/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 287    |
| 609         | 202             | 05/22/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 287    |
| 610         | 202             | 05/22/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 287    |
| 612         | 202             | 05/22/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 290    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|--------|-------------------------------------------|-------------------------|-------------|-----|-----------------------------|--------|--------|
| 613         | 202             | 05/22/2014                     |                | Px        | 99232       | Inpt | Grpract            | 1      | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                             | TEDN   | 290    |
| 614         | 202             | 05/22/2014                     |                | Px        | 99232       | Inpt | Grpract            | 1      | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                             | TEDN   | 291    |
| 611         | 202             | 05/22/2014                     |                | Px        | 99238       | Inpt | Fp                 | 1      | Hospital Discharge Day Management 30 Min/ |                         |             |     |                             | TEDN   | 287    |
| 599         | 202             | 05/22/2014                     |                | Dx        | 79902       |      | Medic              | 1      | Hypoxemia                                 |                         |             |     |                             | TEDN   | 288    |
| 600         | 202             | 05/22/2014                     |                | Px        | E0431       |      | Medic              | 1      | Portable Gaseous O2                       |                         |             |     |                             | TEDN   | 288    |
| 601         | 202             | 05/22/2014                     |                | Px        | E1390       |      | Medic              | 1      | Oxygen Concentrator                       |                         |             |     |                             | TEDN   | 289    |
| 602         | 202             | 05/22/2014                     |                | Rx        | 59762306001 |      |                    |        |                                           | Azithromycin            | 8           | 12  | Tablet                      | PDTS   | 282    |
| 603         | 202             | 05/22/2014                     |                | Rx        | 00597002402 |      |                    |        |                                           | Combivent Respimat      | 25          | 4   | Aerosol W/Adapter (Gm)      | PDTS   | 283    |
| 604         | 202             | 05/22/2014                     |                | Rx        | 00603459315 |      |                    |        |                                           | Methylprednisolone      | 6           | 21  | Tablet, Dose Pack           | PDTS   | 284    |
| 605         | 202             | 05/22/2014                     |                | Rx        | 45802065087 |      |                    |        |                                           | Loratadine              | 30          | 30  | Tablet                      | PDTS   | 285    |
| 606         | 202             | 05/22/2014                     |                | Rx        | 64980015701 |      |                    |        |                                           | Vitamin D2              | 70          | 10  | Capsule (Hard, Soft, Etc.)  | PDTS   | 286    |
| 615         | 204             | 05/24/2014                     |                | Rx        | 68382002810 |      |                    |        |                                           | Metformin Hcl           | 90          | 90  | Tablet                      | PDTS   | 292    |
| 616         | 207             | 05/27/2014                     |                | Rx        | 00603646832 |      |                    |        |                                           | Zolpidem Tartrate       | 30          | 30  | Tablet                      | PDTS   | 293    |
| 617         | 212             | 06/01/2014                     |                | Dx        | 7213        |      | Radio              | 1      | Lumbosacral Spondylosis                   |                         |             |     |                             | TEDN   | 294    |
| 618         | 212             | 06/01/2014                     |                | Dx        | 7242        |      | Radio              | 2      | Lumbago                                   |                         |             |     |                             | TEDN   | 294    |
| 619         | 212             | 06/01/2014                     |                | Px        | 72131       |      | Radio              | 1      | Ct Lumbar Spine W/O Contrast Material     |                         |             |     |                             | TEDN   | 294    |
| 620         | 212             | 06/01/2014                     |                | Px        | 71010       |      | Radio              | 1      | Radiologic Examination Chest Single View  |                         |             |     |                             | TEDN   | 295    |
| 621         | 212             | 06/01/2014                     |                | Dx        | 7242        |      | Grpract            | 1      | Lumbago                                   |                         |             |     |                             | TEDN   | 296    |
| 622         | 212             | 06/01/2014                     |                | Px        | 99285       |      | Grpract            | 1      | Emergency Dept Visit High Severity&threat |                         |             |     |                             | TEDN   | 296    |
| 623         | 212             | 06/01/2014                     |                | Dx        | 33819       |      | Facility           | 1      | Other Acute Pain                          |                         |             |     |                             | TEDN   | 297    |
| 624         | 212             | 06/01/2014                     |                | Dx        | 7245        |      | Facility           | 2      | Backache Unspecified                      |                         |             |     |                             | TEDN   | 297    |
| 625         | 212             | 06/01/2014                     |                | Dx        | 4019        |      | Facility           | 3      | Unspecified Essential Hypertension        |                         |             |     |                             | TEDN   | 297    |
| 626         | 212             | 06/01/2014                     |                | Dx        | 25000       |      | Facility           | 4      | Diabetes Uncompl Type Ii                  |                         |             |     |                             | TEDN   | 297    |
| 627         | 212             | 06/01/2014                     |                | Dx        | 53081       |      | Facility           | 5      | Esophageal Reflux                         |                         |             |     |                             | TEDN   | 297    |
| 628         | 212             | 06/01/2014                     |                | Dx        | 42731       |      | Facility           | 6      | Atrial Fibrillation                       |                         |             |     |                             | TEDN   | 297    |
| 629         | 212             | 06/01/2014                     |                | Px        | 71010       |      | Facility           | 1      | Radiologic Examination Chest Single View  |                         |             |     |                             | TEDN   | 297    |
| 630         | 212             | 06/01/2014                     |                | Px        | 72131       |      | Facility           | 1      | Ct Lumbar Spine W/O Contrast Material     |                         |             |     |                             | TEDN   | 298    |
| 631         | 212             | 06/01/2014                     |                | Px        | 81001       |      | Facility           | 1      | Urnl Dip Stick/Tablet Reagent Auto Micro  |                         |             |     |                             | TEDN   | 299    |
| 632         | 212             | 06/01/2014                     |                | Px        | 87086       |      | Facility           | 1      | Culture Bacterial Quanttative Colony Coun |                         |             |     |                             | TEDN   | 300    |
| 633         | 212             | 06/01/2014                     |                | Px        | 93005       |      | Facility           | 1      | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                         |             |     |                             | TEDN   | 301    |
| 634         | 212             | 06/01/2014                     |                | Px        | 99281       |      | Facility           | 1      | Emergency Department Visit Limited/Minor  |                         |             |     |                             | TEDN   | 302    |
| 635         | 212             | 06/01/2014                     |                | Px        | 99283       |      | Facility           | 1      | Emergency Department Visit Moderate Sever |                         |             |     |                             | TEDN   | 303    |
| 636         | 212             | 06/01/2014                     |                | Px        | C9399       |      | Facility           | 1      | Unclassified Drugs Or Biolog              |                         |             |     |                             | TEDN   | 304    |
| 637         | 213             | 06/02/2014                     |                | Rx        | 00406051205 |      |                    |        |                                           | Oxycodone-Acetaminophen | 3           | 12  | Tablet                      | PDTS   | 305    |
| 638         | 217             | 06/06/2014                     |                | Rx        | 00071101468 |      |                    |        |                                           | Lyrica                  | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 306    |
| 639         | 222             | 06/11/2014                     |                | Dx        | 72252       |      | Ortho              | 1      | Degener Lumbar/Lumbosacral Iv Disc        |                         |             |     |                             | TEDN   | 313    |
| 640         | 222             | 06/11/2014                     |                | Dx        | 7213        |      | Ortho              | 2      | Lumbosacral Spondylosis                   |                         |             |     |                             | TEDN   | 313    |
| 641         | 222             | 06/11/2014                     |                | Px        | 99214       |      | Ortho              | 1      | Office Outpatient Visit 25 Minutes        |                         |             |     |                             | TEDN   | 313    |
| 642         | 222             | 06/11/2014                     |                | Rx        | 00310075290 |      |                    |        |                                           | Crestor                 | 90          | 90  | Tablet                      | PDTS   | 307    |
| 643         | 222             | 06/11/2014                     |                | Rx        | 00008084181 |      |                    |        |                                           | Protonix                | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 308    |
| 644         | 222             | 06/11/2014                     |                | Rx        | 00009519103 |      |                    |        |                                           | Detrol La               | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 309    |
| 645         | 222             | 06/11/2014                     |                | Rx        | 65162062711 |      |                    |        |                                           | Tramadol Hcl            | 30          | 90  | Tablet                      | PDTS   | 310    |
| 646         | 222             | 06/11/2014                     |                | Rx        | 00603258221 |      |                    |        |                                           | Carisoprodol            | 30          | 90  | Tablet                      | PDTS   | 311    |

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Age: 72 Gender: F Indexdate: 11/01/2013 Event Date: 05/15/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code          | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description     | Medication Description     | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|---------------|-----|--------------------|-------|------------------------------------------|----------------------------|-------------|-----|--------------------------------|--------|--------|
| 647         | 222             | 06/11/2014                     |                | Rx        | 00378108901   |     |                    |       |                                          | Meloxicam                  | 90          | 90  | Tablet                         | PDTS   | 312    |
| 648         | 229             | 06/18/2014                     |                | Dx        | 7823          |     | Fp                 | 1     | Edema                                    |                            |             |     |                                | TEDN   | 314    |
| 649         | 229             | 06/18/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes       |                            |             |     |                                | TEDN   | 314    |
| 650         | 230             | 06/19/2014                     |                | Rx        | 00781196610   |     |                    |       |                                          | Furosemide                 | 30          | 15  | Tablet                         | PDTS   | 315    |
| 651         | 230             | 06/19/2014                     |                | Rx        | 00781572010   |     |                    |       |                                          | Potassium Chloride         | 30          | 15  | Tablet, SR, particles/Crystals | PDTS   | 316    |
| 652         | 233             | 06/22/2014                     |                | Dx        | 79902         |     | Medic              | 1     | Hypoxemia                                |                            |             |     |                                | TEDN   | 317    |
| 653         | 233             | 06/22/2014                     |                | Px        | E0431         |     | Medic              | 1     | Portable Gaseous O2                      |                            |             |     |                                | TEDN   | 317    |
| 654         | 233             | 06/22/2014                     |                | Px        | E1390         |     | Medic              | 1     | Oxygen Concentrator                      |                            |             |     |                                | TEDN   | 318    |
| 655         | 238             | 06/27/2014                     |                | Dx        | 42731         |     | Cardvasc           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 321    |
| 656         | 238             | 06/27/2014                     |                | Dx        | 4011          |     | Cardvasc           | 2     | Benign Essential Hypertension            |                            |             |     |                                | TEDN   | 321    |
| 657         | 238             | 06/27/2014                     |                | Dx        | 41401         |     | Cardvasc           | 3     | Atheroscler Native Coronary Art          |                            |             |     |                                | TEDN   | 321    |
| 658         | 238             | 06/27/2014                     |                | Dx        | 496           |     | Cardvasc           | 4     | Chronic Airway Obstruction Other         |                            |             |     |                                | TEDN   | 321    |
| 659         | 238             | 06/27/2014                     |                | Px        | 99215         |     | Cardvasc           | 1     | Office Outpatient Visit 40 Minutes       |                            |             |     |                                | TEDN   | 321    |
| 660         | 238             | 06/27/2014                     |                | Rx        | 64679073402   |     |                    |       |                                          | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr                | PDTS   | 319    |
| 661         | 238             | 06/27/2014                     |                | Rx        | NI Study Drug |     |                    |       |                                          | Non-Index Study Drug       | 90          |     | INITIAL FILL                   | PDTS   | 320    |
| 662         | 243             | 07/02/2014                     |                | Dx        | 42731         |     | Grpprac            | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 322    |
| 663         | 243             | 07/02/2014                     |                | Px        | 93010         |     | Grpprac            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only  |                            |             |     |                                | TEDN   | 322    |
| 664         | 243             | 07/02/2014                     |                | Dx        | 42731         |     | Facility           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 323    |
| 665         | 243             | 07/02/2014                     |                | Px        | 93005         |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only |                            |             |     |                                | TEDN   | 323    |
| 666         | 248             | 07/07/2014                     |                | Rx        | 00071101468   |     |                    |       |                                          | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)     | PDTS   | 324    |
| 667         | 266             | 07/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                          | Eliquis                    | 30          | 60  | Tablet                         | PDTS   | 325    |
| 668         | 269             | 07/28/2014                     |                | Dx        | 25060         |     | Podia              | 1     | Diabetes Neuro Manif Type Ii             |                            |             |     |                                | TEDN   | 328    |
| 669         | 269             | 07/28/2014                     |                | Dx        | 7030          |     | Podia              | 2     | Ingrowing Nail                           |                            |             |     |                                | TEDN   | 328    |
| 670         | 269             | 07/28/2014                     |                | Dx        | 1101          |     | Podia              | 3     | Dermatophytosis Nail                     |                            |             |     |                                | TEDN   | 328    |
| 671         | 269             | 07/28/2014                     |                | Dx        | 7039          |     | Podia              | 4     | Unspec Disease Nail                      |                            |             |     |                                | TEDN   | 328    |
| 672         | 269             | 07/28/2014                     |                | Dx        | 3556          |     | Podia              | 5     | Lesion Plantar Nerve                     |                            |             |     |                                | TEDN   | 328    |
| 673         | 269             | 07/28/2014                     |                | Dx        | 73037         |     | Podia              | 6     | Periostitis Ankle/Foot                   |                            |             |     |                                | TEDN   | 328    |
| 674         | 269             | 07/28/2014                     |                | Dx        | 73399         |     | Podia              | 7     | Other Disorders Bone/Cartilage           |                            |             |     |                                | TEDN   | 328    |
| 675         | 269             | 07/28/2014                     |                | Px        | 11719         |     | Podia              | 1     | Trimming Nondystrophic Nails Any Number  |                            |             |     |                                | TEDN   | 328    |
| 676         | 269             | 07/28/2014                     |                | Px        | 11720         |     | Podia              | 1     | Debridement Nail Any Method 1-5          |                            |             |     |                                | TEDN   | 329    |
| 677         | 269             | 07/28/2014                     |                | Px        | 99212         |     | Podia              | 1     | Office Outpatient Visit 10 Minutes       |                            |             |     |                                | TEDN   | 330    |
| 678         | 269             | 07/28/2014                     |                | Rx        | 00003089421   |     |                    |       |                                          | Eliquis                    | 30          | 60  | Tablet                         | PDTS   | 326    |
| 679         | 269             | 07/28/2014                     |                | Rx        | 00078037905   |     |                    |       |                                          | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.)     | PDTS   | 327    |
| 680         | 277             | 08/05/2014                     |                | Rx        | 00904584940   |     |                    |       |                                          | Metformin Hcl              | 90          | 90  | Tablet                         | PDTS   | 331    |
| 681         | 283             | 08/11/2014                     |                | Rx        | 00071101468   |     |                    |       |                                          | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)     | PDTS   | 332    |
| 682         | 284             | 08/12/2014                     |                | Rx        | 66993089845   |     |                    |       |                                          | Clotrimazole-Betamethasone | 7           | 45  | Cream (Grams)                  | PDTS   | 333    |
| 683         | 286             | 08/14/2014                     |                | Dx        | 42731         |     | Cardvasc           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 334    |
| 684         | 286             | 08/14/2014                     |                | Dx        | 4011          |     | Cardvasc           | 2     | Benign Essential Hypertension            |                            |             |     |                                | TEDN   | 334    |
| 685         | 286             | 08/14/2014                     |                | Dx        | 41401         |     | Cardvasc           | 3     | Atheroscler Native Coronary Art          |                            |             |     |                                | TEDN   | 334    |
| 686         | 286             | 08/14/2014                     |                | Dx        | 496           |     | Cardvasc           | 4     | Chronic Airway Obstruction Other         |                            |             |     |                                | TEDN   | 334    |
| 687         | 286             | 08/14/2014                     |                | Px        | 99214         |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes       |                            |             |     |                                | TEDN   | 334    |
| 688         | 301             | 08/29/2014                     |                | Dx        | 25000         |     | Fp                 | 1     | Diabetes Uncompl Type Ii                 |                            |             |     |                                | TEDN   | 338    |
| 689         | 301             | 08/29/2014                     |                | Dx        | 2810          |     | Fp                 | 2     | Pernicious Anemia                        |                            |             |     |                                | TEDN   | 338    |

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Age: 72 Gender: F Indexdate: 11/01/2013 Event Date: 05/15/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code          | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description       | Medication Description      | Days Supply | QTY | Drug Formulation            | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|---------------|-----|--------------------|-------|--------------------------------------------|-----------------------------|-------------|-----|-----------------------------|--------|--------|
| 690         | 301             | 08/29/2014                     |                | Dx        | 4659          |     | Fp                 | 3     | Acute Upper Resp Infections Uns            |                             |             |     |                             | TEDN   | 338    |
| 691         | 301             | 08/29/2014                     |                | Dx        | 460           |     | Fp                 | 4     | Acute Nasopharyngitis                      |                             |             |     |                             | TEDN   | 338    |
| 692         | 301             | 08/29/2014                     |                | Px        | 80053         |     | Fp                 | 1     | Comprehensive Metabolic Panel              |                             |             |     |                             | TEDN   | 338    |
| 693         | 301             | 08/29/2014                     |                | Px        | 85025         |     | Fp                 | 1     | Blood Count Complete Auto&auto Difrntrl Wb |                             |             |     |                             | TEDN   | 339    |
| 694         | 301             | 08/29/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                             | TEDN   | 340    |
| 695         | 301             | 08/29/2014                     |                | Rx        | 59746012110   |     |                    |       |                                            | Meclizine Hcl               | 10          | 40  | Tablet                      | PDTS   | 335    |
| 696         | 301             | 08/29/2014                     |                | Rx        | 00378363705   |     |                    |       |                                            | Cetirizine Hcl              | 30          | 30  | Tablet                      | PDTS   | 336    |
| 697         | 301             | 08/29/2014                     |                | Rx        | 00781261305   |     |                    |       |                                            | Amoxicillin                 | 10          | 30  | Capsule (Hard, Soft, Etc.)  | PDTS   | 337    |
| 698         | 306             | 09/03/2014                     |                | Rx        | 0             |     |                    |       |                                            | Compounded Medication       | 10          | 240 |                             | PDTS   | 341    |
| 699         | 311             | 09/08/2014                     |                | Dx        | 4659          |     | Fp                 | 1     | Acute Upper Resp Infections Uns            |                             |             |     |                             | TEDN   | 345    |
| 700         | 311             | 09/08/2014                     |                | Dx        | 25000         |     | Fp                 | 2     | Diabetes Uncompl Type Ii                   |                             |             |     |                             | TEDN   | 345    |
| 701         | 311             | 09/08/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                             | TEDN   | 345    |
| 702         | 311             | 09/08/2014                     |                | Rx        | 00093227534   |     |                    |       |                                            | Amox Tr-Potassium Clavulana | 10          | 20  | Tablet                      | PDTS   | 342    |
| 703         | 311             | 09/08/2014                     |                | Rx        | 14550051204   |     |                    |       |                                            | Gabapentin                  | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 343    |
| 704         | 311             | 09/08/2014                     |                | Rx        | 57664018534   |     |                    |       |                                            | Promethazine-Codeine        | 18          | 180 | Syrup                       | PDTS   | 344    |
| 705         | 326             | 09/23/2014                     |                | Rx        | 68001016208   |     |                    |       |                                            | Promethazine Hcl            | 10          | 30  | Tablet                      | PDTS   | 346    |
| 706         | 327             | 09/24/2014                     |                | Rx        | NI Study Drug |     |                    |       |                                            | Non-Index Study Drug        | 90          |     | REFILL                      | PDTS   | 347    |
| 707         | 328             | 09/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                            | Eliquis                     | 30          | 60  | Tablet                      | PDTS   | 348    |
| 708         | 328             | 09/25/2014                     |                | Rx        | 00009519103   |     |                    |       |                                            | Detrol La                   | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 349    |
| 709         | 328             | 09/25/2014                     |                | Rx        | 00008084181   |     |                    |       |                                            | Protonix                    | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 350    |
| 710         | 328             | 09/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                            | Eliquis                     | 30          | 60  | Tablet                      | PDTS   | 351    |
| 711         | 328             | 09/25/2014                     |                | Rx        | 00310075290   |     |                    |       |                                            | Crestor                     | 90          | 90  | Tablet                      | PDTS   | 352    |
| 712         | 329             | 09/26/2014                     |                | Rx        | 00071101468   |     |                    |       |                                            | Lyrica                      | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 353    |

End of Profile



Patient ID: ILD-0088

Age: 71 Gender: F Indexdate: 10/03/2011 Event Date: 07/16/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description     | Medication Description      | Days Supply | QTY | Drug Formulation              | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|------------------------------------------|-----------------------------|-------------|-----|-------------------------------|--------|--------|
| 1           | -329            | 11/08/2010                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 1      |
| 2           | -307            | 11/30/2010                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 2      |
| 3           | -307            | 11/30/2010                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 3      |
| 4           | -307            | 11/30/2010                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 4      |
| 5           | -294            | 12/13/2010                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 5      |
| 6           | -278            | 12/29/2010                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 6      |
| 7           | -266            | 01/10/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 7      |
| 8           | -235            | 02/10/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 90          | 90  | Tablet                        | PDTS   | 8      |
| 9           | -229            | 02/16/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 9      |
| 10          | -229            | 02/16/2011                     |                | Px        | A7032       |     | Medic              | 1     | Replacement Nasal Cushion                |                             |             |     |                               | TEDN   | 9      |
| 11          | -229            | 02/16/2011                     |                | Px        | A7034       |     | Medic              | 1     | Nasal Application Device                 |                             |             |     |                               | TEDN   | 10     |
| 12          | -229            | 02/16/2011                     |                | Px        | A7035       |     | Medic              | 1     | Pos Airway Press Headgear                |                             |             |     |                               | TEDN   | 11     |
| 13          | -229            | 02/16/2011                     |                | Px        | A7037       |     | Medic              | 1     | Pos Airway Pressure Tubing               |                             |             |     |                               | TEDN   | 12     |
| 14          | -217            | 02/28/2011                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 13     |
| 15          | -217            | 02/28/2011                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 14     |
| 16          | -217            | 02/28/2011                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 15     |
| 17          | -185            | 04/01/2011                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 16     |
| 18          | -166            | 04/20/2011                     |                | Dx        | 496         |     | Medic              | 1     | Chronic Airway Obstruction Other         |                             |             |     |                               | TEDN   | 17     |
| 19          | -166            | 04/20/2011                     |                | Px        | J7620       |     | Medic              | 1     | Albuterol Ipratrop Non-Comp              |                             |             |     |                               | TEDN   | 17     |
| 20          | -166            | 04/20/2011                     |                | Px        | Q0513       |     | Medic              | 1     | Disp Fee Inhal Drugs/30 Days             |                             |             |     |                               | TEDN   | 18     |
| 21          | -165            | 04/21/2011                     |                | Dx        | 32723       |     | Indeplab           | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 19     |
| 22          | -165            | 04/21/2011                     |                | Px        | 94762       |     | Indeplab           | 1     | Noninvasive Ear/Pulse Oximetry Overnight |                             |             |     |                               | TEDN   | 19     |
| 23          | -159            | 04/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 20     |
| 24          | -159            | 04/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 20     |
| 25          | -140            | 05/16/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 90          | 90  | Tablet                        | PDTS   | 21     |
| 26          | -130            | 05/26/2011                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 22     |
| 27          | -129            | 05/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 24     |
| 28          | -129            | 05/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 24     |
| 29          | -129            | 05/27/2011                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 23     |
| 30          | -124            | 06/01/2011                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 25     |
| 31          | -101            | 06/24/2011                     |                | Rx        | 59310057920 |     |                    |       |                                          | Proair Hfa                  | 25          | 9   | Hfa Aerosol With Adapter (Gm) | PDTS   | 26     |
| 32          | -101            | 06/24/2011                     |                | Rx        | 00085128801 |     |                    |       |                                          | Nasonex                     | 30          | 17  | Aerosol, Spray W/Pump (Gm)    | PDTS   | 27     |
| 33          | -98             | 06/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 28     |
| 34          | -98             | 06/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 28     |
| 35          | -96             | 06/29/2011                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 29     |
| 36          | -68             | 07/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 30     |
| 37          | -68             | 07/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 30     |
| 38          | -49             | 08/15/2011                     |                | Dx        | 2449        |     | Fp                 | 1     | Uns Hypothyroidism                       |                             |             |     |                               | TEDN   | 37     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 39          | -49             | 08/15/2011                     |                | Dx        | 69010       |     | Fp                 | 2     | Uns Seborrheic Dermatitis                 |                             |             |     |                              | TEDN   | 37     |
| 40          | -49             | 08/15/2011                     |                | Dx        | 79021       |     | Fp                 | 3     | Impaired Fasting Glucose                  |                             |             |     |                              | TEDN   | 37     |
| 41          | -49             | 08/15/2011                     |                | Dx        | 4019        |     | Fp                 | 4     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 37     |
| 42          | -49             | 08/15/2011                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 37     |
| 43          | -49             | 08/15/2011                     |                | Rx        | 00085128801 |     |                    |       |                                           | Nasonex                     | 30          | 17  | Aerosol, Spray W/Pump (Gm)   | PDTS   | 31     |
| 44          | -49             | 08/15/2011                     |                | Rx        | 00186504031 |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 32     |
| 45          | -49             | 08/15/2011                     |                | Rx        | 65862019201 |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 33     |
| 46          | -49             | 08/15/2011                     |                | Rx        | 00527134210 |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 34     |
| 47          | -49             | 08/15/2011                     |                | Rx        | 45802046564 |     |                    |       |                                           | Ketoconazole                | 30          | 240 | Shampoo                      | PDTS   | 35     |
| 48          | -49             | 08/15/2011                     |                | Rx        | 68462055401 |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 36     |
| 49          | -39             | 08/25/2011                     |                | Dx        | 4011        |     | Cardvasc           | 1     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 41     |
| 50          | -39             | 08/25/2011                     |                | Dx        | 42731       |     | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 41     |
| 51          | -39             | 08/25/2011                     |                | Dx        | 2865        |     | Cardvasc           | 3     | Intrin Circ Anticoag Hemorr Dis           |                             |             |     |                              | TEDN   | 41     |
| 52          | -39             | 08/25/2011                     |                | Px        | 93000       |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                             |             |     |                              | TEDN   | 41     |
| 53          | -39             | 08/25/2011                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 42     |
| 54          | -39             | 08/25/2011                     |                | Rx        | 62037059990 |     |                    |       |                                           | Cartia Xt                   | 90          | 90  | Capsule, SR 24 Hr            | PDTS   | 38     |
| 55          | -39             | 08/25/2011                     |                | Rx        | 00527132410 |     |                    |       |                                           | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 39     |
| 56          | -39             | 08/25/2011                     |                | Rx        | 51672403201 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 40     |
| 57          | -37             | 08/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 43     |
| 58          | -37             | 08/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 43     |
| 59          | -35             | 08/29/2011                     |                | Dx        | V5861       |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 44     |
| 60          | -35             | 08/29/2011                     |                | Dx        | 42731       |     | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 44     |
| 61          | -35             | 08/29/2011                     |                | Px        | 85610       |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 44     |
| 62          | -35             | 08/29/2011                     |                | Px        | 99211       |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 45     |
| 72          | -29             | 09/04/2011                     |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 47     |
| 73          | -29             | 09/04/2011                     |                | Px        | 93010       |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                             |             |     |                              | TEDN   | 47     |
| 63          | -29             | 09/04/2011                     |                | Dx        | 5789        |     | Gp                 | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                              | TEDN   | 46     |
| 64          | -29             | 09/04/2011                     |                | Dx        | 5693        |     | Gp                 | 2     | Hemorrhage Rectum/Anus                    |                             |             |     |                              | TEDN   | 46     |
| 65          | -29             | 09/04/2011                     |                | Dx        | 42731       |     | Gp                 | 3     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 46     |
| 66          | -29             | 09/04/2011                     |                | Dx        | 53081       |     | Gp                 | 4     | Esophageal Reflux                         |                             |             |     |                              | TEDN   | 46     |
| 67          | -29             | 09/04/2011                     |                | Dx        | 2449        |     | Gp                 | 5     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 46     |
| 68          | -29             | 09/04/2011                     |                | Dx        | 4019        |     | Gp                 | 6     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 46     |
| 69          | -29             | 09/04/2011                     |                | Dx        | 56210       |     | Gp                 | 7     | Diverticulosis Colon                      |                             |             |     |                              | TEDN   | 46     |
| 70          | -29             | 09/04/2011                     |                | Dx        | V4586       |     | Gp                 | 8     | Bariatric Surgery Status                  |                             |             |     |                              | TEDN   | 46     |
| 71          | -29             | 09/04/2011                     |                | Px        | 99283       |     | Gp                 | 1     | Emergency Department Visit Moderate Sever |                             |             |     |                              | TEDN   | 46     |
| 74          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 5789        |     |                    | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                              | TEDI   | 50     |
| 75          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 42731       |     |                    | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDI   | 50     |
| 76          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 53081       |     |                    | 3     | Esophageal Reflux                         |                             |             |     |                              | TEDI   | 50     |



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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 77          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 2449  |      |                    | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDI   | 50     |
| 78          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 4019  |      |                    | 5     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 50     |
| 79          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 56210 |      |                    | 6     | Diverticulosis Colon                      |                        |             |     |                  | TEDI   | 50     |
| 80          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | V4586 |      |                    | 7     | Bariatric Surgery Status                  |                        |             |     |                  | TEDI   | 50     |
| 81          | -29             | 09/04/2011                     | 09/07/2011     | Px        | 4513  |      |                    | 1     | Sm Bowel Endoscopy Other Spec             |                        |             |     |                  | TEDI   | 50     |
| 82          | -29             | 09/04/2011                     | 09/07/2011     | Px        | 4523  |      |                    | 2     | Colonoscopy                               |                        |             |     |                  | TEDI   | 50     |
| 83          | -29             | 09/04/2011                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 48     |
| 84          | -29             | 09/04/2011                     |                | Dx        | 78650 | Inpt | Radio              | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 49     |
| 85          | -29             | 09/04/2011                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 49     |
| 86          | -27             | 09/06/2011                     |                | Dx        | 5789  | Inpt | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 51     |
| 87          | -27             | 09/06/2011                     |                | Dx        | 56210 | Inpt | Grppract           | 2     | Diverticulosis Colon                      |                        |             |     |                  | TEDN   | 51     |
| 88          | -27             | 09/06/2011                     |                | Px        | 43235 | Inpt | Grppract           | 1     | Upper Gi Ndsc Dx W/Wo Collection Specimen |                        |             |     |                  | TEDN   | 51     |
| 89          | -27             | 09/06/2011                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 52     |
| 90          | -26             | 09/07/2011                     |                | Dx        | 5789  | Inpt | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 53     |
| 91          | -26             | 09/07/2011                     |                | Dx        | 56210 | Inpt | Grppract           | 2     | Diverticulosis Colon                      |                        |             |     |                  | TEDN   | 53     |
| 92          | -26             | 09/07/2011                     |                | Px        | 45378 | Inpt | Grppract           | 1     | Colonoscopy Flx Dx W/Wo Collj Specimens   |                        |             |     |                  | TEDN   | 53     |
| 93          | -18             | 09/15/2011                     |                | Dx        | 4011  |      | Cardvasc           | 1     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 54     |
| 94          | -18             | 09/15/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 54     |
| 95          | -18             | 09/15/2011                     |                | Px        | 93000 |      | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                        |             |     |                  | TEDN   | 54     |
| 96          | -18             | 09/15/2011                     |                | Px        | 99213 |      | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                  | TEDN   | 55     |
| 97          | -14             | 09/19/2011                     |                | Dx        | 42731 |      | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 56     |
| 98          | -14             | 09/19/2011                     |                | Dx        | 4011  |      | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 56     |
| 99          | -14             | 09/19/2011                     |                | Px        | 93312 |      | Cardvasc           | 1     | Ecg Transesophag R-T 2d W/Prb Img Acquisj |                        |             |     |                  | TEDN   | 56     |
| 100         | -14             | 09/19/2011                     |                | Px        | 93320 |      | Cardvasc           | 1     | Doppler Echocard Pulse Wave W/Spectral Di |                        |             |     |                  | TEDN   | 57     |
| 101         | -14             | 09/19/2011                     |                | Px        | 93325 |      | Cardvasc           | 1     | Dop Echocard Color Flow Velocity Mapping  |                        |             |     |                  | TEDN   | 58     |
| 102         | -14             | 09/19/2011                     |                | Dx        | 42731 |      | Facility           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 59     |
| 103         | -14             | 09/19/2011                     |                | Dx        | V641  |      | Facility           | 2     | Px Not Done Contraindication              |                        |             |     |                  | TEDN   | 59     |
| 104         | -14             | 09/19/2011                     |                | Px        | 93005 |      | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                  | TEDN   | 59     |
| 105         | -12             | 09/21/2011                     |                | Dx        | V5861 |      | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 60     |
| 106         | -12             | 09/21/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 60     |
| 107         | -12             | 09/21/2011                     |                | Px        | 85610 |      | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 60     |
| 108         | -12             | 09/21/2011                     |                | Px        | 99211 |      | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 61     |
| 109         | -6              | 09/27/2011                     |                | Dx        | 32723 |      | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                  | TEDN   | 62     |
| 110         | -6              | 09/27/2011                     |                | Px        | E1390 |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 62     |
| 111         | -5              | 09/28/2011                     |                | Dx        | V5861 |      | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 63     |
| 112         | -5              | 09/28/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 63     |
| 113         | -5              | 09/28/2011                     |                | Px        | 85610 |      | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 63     |
| 114         | -5              | 09/28/2011                     |                | Px        | 99211 |      | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 64     |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 115         | 0               | 10/03/2011                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 66     |
| 116         | 0               | 10/03/2011                     |                | Dx        | 28652            |     | Cardvasc           | 2     | Acquired Hemophilia                  |                             |             |     |                              | TEDN   | 66     |
| 117         | 0               | 10/03/2011                     |                | Px        | 93000            |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r |                             |             |     |                              | TEDN   | 66     |
| 118         | 0               | 10/03/2011                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes   |                             |             |     |                              | TEDN   | 67     |
| 119         | 0               | 10/03/2011                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | INITIAL FILL                 | PDTS   | 65     |
| 120         | 8               | 10/11/2011                     |                | Rx        | 51672403201      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 68     |
| 121         | 16              | 10/19/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 69     |
| 122         | 16              | 10/19/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 69     |
| 123         | 16              | 10/19/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 69     |
| 124         | 16              | 10/19/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 70     |
| 125         | 23              | 10/26/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 71     |
| 126         | 23              | 10/26/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 71     |
| 127         | 23              | 10/26/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 71     |
| 128         | 23              | 10/26/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 72     |
| 129         | 24              | 10/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 73     |
| 130         | 24              | 10/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 73     |
| 131         | 35              | 11/07/2011                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 74     |
| 132         | 35              | 11/07/2011                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis   |                             |             |     |                              | TEDN   | 74     |
| 133         | 35              | 11/07/2011                     |                | Px        | 99212            |     | Cardvasc           | 1     | Office Outpatient Visit 10 Minutes   |                             |             |     |                              | TEDN   | 74     |
| 134         | 50              | 11/22/2011                     |                | Rx        | 00527132410      |     |                    |       |                                      | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 75     |
| 135         | 50              | 11/22/2011                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 76     |
| 136         | 55              | 11/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 77     |
| 137         | 55              | 11/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 77     |
| 138         | 56              | 11/28/2011                     |                | Rx        | 65862019201      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 78     |
| 139         | 57              | 11/29/2011                     |                | Rx        | 59762525004      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 79     |
| 140         | 57              | 11/29/2011                     |                | Rx        | 00186504031      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 80     |
| 141         | 59              | 12/01/2011                     |                | Rx        | 51672403201      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 81     |
| 142         | 63              | 12/05/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 82     |
| 143         | 63              | 12/05/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 82     |
| 144         | 63              | 12/05/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 82     |
| 145         | 63              | 12/05/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 83     |
| 146         | 78              | 12/20/2011                     |                | Rx        | 00527134210      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 84     |
| 147         | 84              | 12/26/2011                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 85     |
| 148         | 85              | 12/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 86     |
| 149         | 85              | 12/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 86     |
| 150         | 98              | 01/09/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 87     |
| 151         | 98              | 01/09/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 87     |
| 152         | 98              | 01/09/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 87     |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 153         | 98              | 01/09/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 88     |
| 154         | 113             | 01/24/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 89     |
| 155         | 113             | 01/24/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 90     |
| 156         | 116             | 01/27/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 91     |
| 157         | 116             | 01/27/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 91     |
| 158         | 116             | 01/27/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 92     |
| 159         | 116             | 01/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 93     |
| 160         | 116             | 01/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 93     |
| 161         | 135             | 02/15/2012                     |                | Dx        | 6929             |     | Grppract           | 1     | Contact Dermatitis Uns Cause         |                             |             |     |                              | TEDN   | 100    |
| 162         | 135             | 02/15/2012                     |                | Dx        | 79029            |     | Grppract           | 2     | Other Abnormal Glucose               |                             |             |     |                              | TEDN   | 100    |
| 163         | 135             | 02/15/2012                     |                | Dx        | 27800            |     | Grppract           | 3     | Obesity Unspecified                  |                             |             |     |                              | TEDN   | 100    |
| 164         | 135             | 02/15/2012                     |                | Dx        | 2449             |     | Grppract           | 4     | Uns Hypothyroidism                   |                             |             |     |                              | TEDN   | 100    |
| 165         | 135             | 02/15/2012                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes   |                             |             |     |                              | TEDN   | 100    |
| 166         | 135             | 02/15/2012                     |                | Rx        | 00186504031      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 94     |
| 167         | 135             | 02/15/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 95     |
| 168         | 135             | 02/15/2012                     |                | Rx        | 00115981101      |     |                    |       |                                      | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 96     |
| 169         | 135             | 02/15/2012                     |                | Rx        | 68645013154      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 97     |
| 170         | 135             | 02/15/2012                     |                | Rx        | 00168025846      |     |                    |       |                                      | Clotrimazole-Betamethasone  | 10          | 45  | Cream (Grams)                | PDTS   | 98     |
| 171         | 135             | 02/15/2012                     |                | Rx        | 00781709004      |     |                    |       |                                      | Ketoconazole                | 10          | 240 | Shampoo                      | PDTS   | 99     |
| 172         | 137             | 02/17/2012                     |                | Rx        | 00185034101      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 101    |
| 173         | 147             | 02/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 102    |
| 174         | 147             | 02/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 102    |
| 175         | 161             | 03/12/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 103    |
| 176         | 170             | 03/21/2012                     |                | Rx        | 00378180301      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 104    |
| 177         | 172             | 03/23/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 105    |
| 178         | 172             | 03/23/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 105    |
| 179         | 172             | 03/23/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 105    |
| 180         | 172             | 03/23/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 106    |
| 181         | 176             | 03/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 107    |
| 182         | 176             | 03/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 107    |
| 183         | 200             | 04/20/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 108    |
| 184         | 200             | 04/20/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 108    |
| 185         | 200             | 04/20/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 108    |
| 186         | 200             | 04/20/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 109    |
| 187         | 207             | 04/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 110    |
| 188         | 207             | 04/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 110    |
| 189         | 208             | 04/28/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 111    |
| 190         | 231             | 05/21/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 112    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 191         | 231             | 05/21/2012                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                        |             |     |                              | TEDN   | 112    |
| 192         | 231             | 05/21/2012                     |                | Px        | 93000            |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                        |             |     |                              | TEDN   | 112    |
| 193         | 231             | 05/21/2012                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 113    |
| 194         | 233             | 05/23/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 114    |
| 195         | 233             | 05/23/2012                     |                | Rx        | 68645013154      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 115    |
| 196         | 233             | 05/23/2012                     |                | Rx        | 00186504031      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 116    |
| 197         | 233             | 05/23/2012                     |                | Rx        | 00115981101      |     |                    |       |                                           | Digoxin                | 90          | 90  | Tablet                       | PDTS   | 117    |
| 198         | 237             | 05/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 118    |
| 199         | 237             | 05/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 118    |
| 200         | 254             | 06/13/2012                     |                | Rx        | 68382005601      |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                       | PDTS   | 119    |
| 201         | 254             | 06/13/2012                     |                | Rx        | 00378180301      |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                       | PDTS   | 120    |
| 202         | 259             | 06/18/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                              | TEDN   | 121    |
| 203         | 259             | 06/18/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 121    |
| 204         | 259             | 06/18/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 121    |
| 205         | 259             | 06/18/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 122    |
| 206         | 268             | 06/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 123    |
| 207         | 268             | 06/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 123    |
| 208         | 276             | 07/05/2012                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other          |                        |             |     |                              | TEDN   | 124    |
| 209         | 276             | 07/05/2012                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilal Rspse Spmtry Pre&post-Brncdilal |                        |             |     |                              | TEDN   | 124    |
| 210         | 276             | 07/05/2012                     |                | Px        | 99205            |     | Pulmo              | 1     | Office Outpatient New 60 Minutes          |                        |             |     |                              | TEDN   | 125    |
| 211         | 277             | 07/06/2012                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium        | 84          | 54  | Tablet                       | PDTS   | 126    |
| 212         | 293             | 07/22/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 127    |
| 213         | 293             | 07/22/2012                     |                | Rx        | 50111064702      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 128    |
| 214         | 293             | 07/22/2012                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 129    |
| 215         | 293             | 07/22/2012                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                | 90          | 90  | Tablet                       | PDTS   | 130    |
| 216         | 295             | 07/24/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | REFILL                       | PDTS   | 131    |
| 217         | 298             | 07/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 132    |
| 218         | 298             | 07/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 132    |
| 219         | 304             | 08/02/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                              | TEDN   | 133    |
| 220         | 304             | 08/02/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 133    |
| 221         | 304             | 08/02/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 134    |
| 222         | 304             | 08/02/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                           |                        |             |     |                              | TEDN   | 135    |
| 223         | 304             | 08/02/2012                     |                | Px        | 36600            |     | Pulmo              | 1     | Arterial Puncture Withdrawal Blood Dx     |                        |             |     |                              | TEDN   | 135    |
| 224         | 304             | 08/02/2012                     |                | Px        | 82375            |     | Pulmo              | 1     | Carboxyhemoglobin Quantitative            |                        |             |     |                              | TEDN   | 136    |
| 225         | 304             | 08/02/2012                     |                | Px        | 82803            |     | Pulmo              | 1     | Blood Gases Any Combination Ph Pco2 Po2 C |                        |             |     |                              | TEDN   | 137    |
| 226         | 304             | 08/02/2012                     |                | Px        | 85018            |     | Pulmo              | 1     | Blood Count Hemoglobin                    |                        |             |     |                              | TEDN   | 138    |
| 227         | 304             | 08/02/2012                     |                | Px        | 71250            |     | Pulmo              | 1     | Ct Thorax W/O Contrast Material           |                        |             |     |                              | TEDN   | 139    |
| 228         | 304             | 08/02/2012                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilal Rspse Spmtry Pre&post-Brncdilal |                        |             |     |                              | TEDN   | 140    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 229         | 304             | 08/02/2012                     |                | Px        | 94200            |     | Pulmo              | 1     | Max Breathing Capacity Maximal Voluntary  |                             |             |     |                              | TEDN   | 141    |
| 230         | 304             | 08/02/2012                     |                | Px        | 94726            |     | Pulmo              | 1     | Plethysmography Lung Volumes W/Wo Airway  |                             |             |     |                              | TEDN   | 142    |
| 231         | 304             | 08/02/2012                     |                | Px        | 94729            |     | Pulmo              | 1     | Diffusing Capacity                        |                             |             |     |                              | TEDN   | 143    |
| 232         | 304             | 08/02/2012                     |                | Dx        | 79319            |     | Grpprac            | 1     | Abnormal Findings Lung Field Other        |                             |             |     |                              | TEDN   | 144    |
| 233         | 304             | 08/02/2012                     |                | Px        | 71250            |     | Grpprac            | 1     | Ct Thorax W/O Contrast Material           |                             |             |     |                              | TEDN   | 144    |
| 234         | 314             | 08/12/2012                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 145    |
| 235         | 317             | 08/15/2012                     |                | Dx        | 79029            |     | Fp                 | 1     | Other Abnormal Glucose                    |                             |             |     |                              | TEDN   | 147    |
| 236         | 317             | 08/15/2012                     |                | Dx        | 2449             |     | Fp                 | 2     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 147    |
| 237         | 317             | 08/15/2012                     |                | Dx        | 71690            |     | Fp                 | 3     | Uns Arthropathy Site Uns                  |                             |             |     |                              | TEDN   | 147    |
| 238         | 317             | 08/15/2012                     |                | Dx        | 27800            |     | Fp                 | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 147    |
| 239         | 317             | 08/15/2012                     |                | Px        | 99213            |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 147    |
| 240         | 317             | 08/15/2012                     |                | Dx        | 79029            |     | Grpprac            | 1     | Other Abnormal Glucose                    |                             |             |     |                              | TEDN   | 148    |
| 241         | 317             | 08/15/2012                     |                | Dx        | 2449             |     | Grpprac            | 2     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 148    |
| 242         | 317             | 08/15/2012                     |                | Dx        | 71690            |     | Grpprac            | 3     | Uns Arthropathy Site Uns                  |                             |             |     |                              | TEDN   | 148    |
| 243         | 317             | 08/15/2012                     |                | Dx        | 27800            |     | Grpprac            | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 148    |
| 244         | 317             | 08/15/2012                     |                | Px        | 99499            |     | Grpprac            | 1     | Unlisted Evaluation And Management Servic |                             |             |     |                              | TEDN   | 148    |
| 245         | 317             | 08/15/2012                     |                | Rx        | 65162061710      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 2           | 10  | Tablet                       | PDTS   | 146    |
| 246         | 322             | 08/20/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                           |                             |             |     |                              | TEDN   | 151    |
| 247         | 322             | 08/20/2012                     |                | Dx        | 32723            |     | Pulmo              | 2     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 151    |
| 248         | 322             | 08/20/2012                     |                | Dx        | 4770             |     | Pulmo              | 3     | Allergic Rhinitis Pollen                  |                             |             |     |                              | TEDN   | 151    |
| 249         | 322             | 08/20/2012                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 151    |
| 250         | 322             | 08/20/2012                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 149    |
| 251         | 322             | 08/20/2012                     |                | Rx        | 00597001314      |     |                    |       |                                           | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 150    |
| 252         | 323             | 08/21/2012                     |                | Rx        | 45802046564      |     |                    |       |                                           | Ketoconazole                | 90          | 240 | Shampoo                      | PDTS   | 152    |
| 253         | 328             | 08/26/2012                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 153    |
| 254         | 329             | 08/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 155    |
| 255         | 329             | 08/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 155    |
| 256         | 329             | 08/27/2012                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 154    |
| 257         | 347             | 09/14/2012                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 156    |
| 258         | 353             | 09/20/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 158    |
| 259         | 353             | 09/20/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 158    |
| 260         | 353             | 09/20/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 159    |
| 261         | 353             | 09/20/2012                     |                | Rx        | 50111064702      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 157    |
| 262         | 360             | 09/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 160    |
| 263         | 360             | 09/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 160    |
| 264         | 369             | 10/06/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 161    |
| 265         | 369             | 10/06/2012                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 162    |
| 266         | 369             | 10/06/2012                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 163    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 267         | 374             | 10/11/2012                     |                | Rx        | 00781518110      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 164    |
| 268         | 381             | 10/18/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 165    |
| 269         | 381             | 10/18/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 165    |
| 270         | 381             | 10/18/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 166    |
| 271         | 390             | 10/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 167    |
| 272         | 390             | 10/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 167    |
| 273         | 397             | 11/03/2012                     |                | Rx        | 49884030402      |     |                    |       |                                      | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 168    |
| 274         | 397             | 11/03/2012                     |                | Rx        | 00597001314      |     |                    |       |                                      | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 169    |
| 275         | 399             | 11/05/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                      |                             |             |     |                              | TEDN   | 171    |
| 276         | 399             | 11/05/2012                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes   |                             |             |     |                              | TEDN   | 171    |
| 277         | 399             | 11/05/2012                     |                | Rx        | 00173069600      |     |                    |       |                                      | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 170    |
| 278         | 401             | 11/07/2012                     |                | Rx        | 45802046564      |     |                    |       |                                      | Ketoconazole                | 90          | 240 | Shampoo                      | PDTS   | 172    |
| 279         | 403             | 11/09/2012                     |                | Rx        | 59762525004      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 173    |
| 280         | 421             | 11/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 174    |
| 281         | 421             | 11/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 174    |
| 282         | 424             | 11/30/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 175    |
| 283         | 424             | 11/30/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 175    |
| 284         | 424             | 11/30/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 176    |
| 285         | 426             | 12/02/2012                     |                | Rx        | 50111064702      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 177    |
| 286         | 430             | 12/06/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 178    |
| 287         | 430             | 12/06/2012                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis   |                             |             |     |                              | TEDN   | 178    |
| 288         | 430             | 12/06/2012                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes   |                             |             |     |                              | TEDN   | 178    |
| 289         | 431             | 12/07/2012                     |                | Rx        | 60429078910      |     |                    |       |                                      | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 179    |
| 290         | 451             | 12/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 180    |
| 291         | 451             | 12/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 180    |
| 292         | 455             | 12/31/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 181    |
| 293         | 455             | 12/31/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 181    |
| 294         | 455             | 12/31/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 182    |
| 295         | 459             | 01/04/2013                     |                | Rx        | 00173024275      |     |                    |       |                                      | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 183    |
| 296         | 459             | 01/04/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 184    |
| 297         | 459             | 01/04/2013                     |                | Rx        | 00186504085      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 185    |
| 298         | 465             | 01/10/2013                     |                | Rx        | 00172635960      |     |                    |       |                                      | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 186    |
| 299         | 473             | 01/18/2013                     |                | Rx        | 00173069600      |     |                    |       |                                      | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 187    |
| 300         | 482             | 01/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 188    |
| 301         | 482             | 01/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 188    |
| 302         | 487             | 02/01/2013                     |                | Rx        | 00597001314      |     |                    |       |                                      | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 189    |
| 303         | 487             | 02/01/2013                     |                | Rx        | 49884030402      |     |                    |       |                                      | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 190    |
| 304         | 490             | 02/04/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 191    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 305         | 490             | 02/04/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 191    |
| 306         | 490             | 02/04/2013                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 192    |
| 307         | 506             | 02/20/2013                     |                | Dx        | 2449             |     | Grppract           | 1     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 195    |
| 308         | 506             | 02/20/2013                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 195    |
| 309         | 506             | 02/20/2013                     |                | Dx        | 53081            |     | Grppract           | 3     | Esophageal Reflux                         |                             |             |     |                              | TEDN   | 195    |
| 310         | 506             | 02/20/2013                     |                | Dx        | 27800            |     | Grppract           | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 195    |
| 311         | 506             | 02/20/2013                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 195    |
| 312         | 506             | 02/20/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 193    |
| 313         | 506             | 02/20/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 194    |
| 314         | 513             | 02/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 196    |
| 315         | 513             | 02/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 196    |
| 316         | 515             | 03/01/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 197    |
| 317         | 519             | 03/05/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 198    |
| 318         | 522             | 03/08/2013                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 199    |
| 319         | 532             | 03/18/2013                     |                | Rx        | 00173024275      |     |                    |       |                                           | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 200    |
| 320         | 536             | 03/22/2013                     |                | Rx        | 45802005505      |     |                    |       |                                           | Triamcinolone Acetonide     | 14          | 454 | Ointment(Gm)                 | PDTS   | 201    |
| 321         | 538             | 03/24/2013                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 202    |
| 322         | 541             | 03/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 203    |
| 323         | 541             | 03/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 203    |
| 324         | 549             | 04/04/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 204    |
| 325         | 553             | 04/08/2013                     |                | Dx        | 79380            |     | Fp                 | 1     | Unsp Abnormal Mammogram                   |                             |             |     |                              | TEDN   | 205    |
| 326         | 553             | 04/08/2013                     |                | Px        | 76645            |     | Fp                 | 1     | Us Breast Real Time W/Image Documentation |                             |             |     |                              | TEDN   | 205    |
| 327         | 553             | 04/08/2013                     |                | Px        | 77051            |     | Fp                 | 1     | Computer-Aided Detection Dx Mammography   |                             |             |     |                              | TEDN   | 206    |
| 328         | 553             | 04/08/2013                     |                | Px        | G0206            |     | Fp                 | 1     | Diagnosticmammographydigital              |                             |             |     |                              | TEDN   | 207    |
| 329         | 563             | 04/18/2013                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 208    |
| 330         | 567             | 04/22/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 209    |
| 331         | 567             | 04/22/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 209    |
| 332         | 567             | 04/22/2013                     |                | Dx        | 70211            |     | Derm               | 1     | Inflamed Seborrheic Keratosis             |                             |             |     |                              | TEDN   | 210    |
| 333         | 567             | 04/22/2013                     |                | Px        | 11312            |     | Derm               | 1     | Shvg Skin Lesion 1 F/E/E/N/L/M Diam 1.1-2 |                             |             |     |                              | TEDN   | 210    |
| 334         | 572             | 04/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 211    |
| 335         | 572             | 04/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 211    |
| 336         | 577             | 05/02/2013                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 212    |
| 337         | 580             | 05/05/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 213    |
| 338         | 580             | 05/05/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 214    |
| 339         | 592             | 05/17/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 215    |
| 340         | 600             | 05/25/2013                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 216    |
| 341         | 602             | 05/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 217    |
| 342         | 602             | 05/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 217    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|------------------------------|--------|--------|
| 343         | 611             | 06/05/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                            |             |     |                              | TEDN   | 218    |
| 344         | 611             | 06/05/2013                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                            |             |     |                              | TEDN   | 218    |
| 345         | 611             | 06/05/2013                     |                | Dx        | 42731            |     | Cardvasc           | 3     | Atrial Fibrillation                       |                            |             |     |                              | TEDN   | 218    |
| 346         | 611             | 06/05/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                            |             |     |                              | TEDN   | 218    |
| 347         | 611             | 06/05/2013                     |                | Dx        | 94400            |     | Derm               | 1     | Burn Unsp Of Hand Unspec                  |                            |             |     |                              | TEDN   | 219    |
| 348         | 611             | 06/05/2013                     |                | Dx        | 6959             |     | Derm               | 2     | Uns Erythematous Condition                |                            |             |     |                              | TEDN   | 219    |
| 349         | 611             | 06/05/2013                     |                | Px        | 11100            |     | Derm               | 1     | Bx Skin Subcutaneous&/Mucous Membrane 1 L |                            |             |     |                              | TEDN   | 219    |
| 350         | 611             | 06/05/2013                     |                | Px        | 11101            |     | Derm               | 1     | Biopsy Skin Subq&/Mucous Membrane Ea Addl |                            |             |     |                              | TEDN   | 220    |
| 351         | 611             | 06/05/2013                     |                | Px        | 99213            |     | Derm               | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                              | TEDN   | 221    |
| 352         | 613             | 06/07/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                            |             |     |                              | TEDN   | 222    |
| 353         | 613             | 06/07/2013                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                            |             |     |                              | TEDN   | 222    |
| 354         | 613             | 06/07/2013                     |                | Dx        | 42731            |     | Cardvasc           | 3     | Atrial Fibrillation                       |                            |             |     |                              | TEDN   | 222    |
| 355         | 613             | 06/07/2013                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                              | TEDN   | 222    |
| 356         | 618             | 06/12/2013                     |                | Rx        | 00168016330      |     |                    |       |                                           | Clobetasol Propionate      | 30          | 60  | Cream (Grams)                | PDTS   | 223    |
| 357         | 618             | 06/12/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium            | 90          | 65  | Tablet                       | PDTS   | 224    |
| 358         | 633             | 06/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 225    |
| 359         | 633             | 06/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 225    |
| 360         | 646             | 07/10/2013                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                             |                            |             |     |                              | TEDN   | 227    |
| 361         | 646             | 07/10/2013                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes        |                            |             |     |                              | TEDN   | 227    |
| 362         | 646             | 07/10/2013                     |                | Rx        | 45802005505      |     |                    |       |                                           | Triamcinolone Acetonide    | 90          | 453 | Ointment(Gm)                 | PDTS   | 226    |
| 363         | 647             | 07/11/2013                     |                | Rx        | 60429090230      |     |                    |       |                                           | Clobetasol Propionate      | 30          | 60  | Cream (Grams)                | PDTS   | 228    |
| 364         | 651             | 07/15/2013                     |                | Rx        | 45802046564      |     |                    |       |                                           | Ketoconazole               | 30          | 240 | Shampoo                      | PDTS   | 229    |
| 365         | 651             | 07/15/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG           | 90          |     | REFILL                       | PDTS   | 230    |
| 366         | 651             | 07/15/2013                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen | 90          | 270 | Tablet                       | PDTS   | 231    |
| 367         | 651             | 07/15/2013                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                | 90          | 180 | Tablet                       | PDTS   | 232    |
| 368         | 653             | 07/17/2013                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus              | 90          | 180 | Disk, With Inhalation Device | PDTS   | 233    |
| 369         | 660             | 07/24/2013                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                    | 90          | 90  | Tablet                       | PDTS   | 234    |
| 370         | 663             | 07/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 235    |
| 371         | 663             | 07/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 235    |
| 372         | 666             | 07/30/2013                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other          |                            |             |     |                              | TEDN   | 236    |
| 373         | 666             | 07/30/2013                     |                | Dx        | 32723            |     | Pulmo              | 2     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 236    |
| 374         | 666             | 07/30/2013                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                              | TEDN   | 236    |
| 375         | 670             | 08/03/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl             | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 237    |
| 376         | 670             | 08/03/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium       | 90          | 90  | Tablet                       | PDTS   | 238    |
| 377         | 681             | 08/14/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                     | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 239    |
| 378         | 692             | 08/25/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium            | 90          | 65  | Tablet                       | PDTS   | 240    |
| 379         | 694             | 08/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 241    |
| 380         | 694             | 08/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 241    |



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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-----------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 381         | 703             | 09/05/2013                     |                | Dx        | 4019             |     | Grpprac            | 1     | Unspecified Essential Hypertension      |                             |             |     |                              | TEDN   | 242    |
| 382         | 703             | 09/05/2013                     |                | Dx        | 4280             |     | Grpprac            | 2     | Congestive Heart Failure Unspec         |                             |             |     |                              | TEDN   | 242    |
| 383         | 703             | 09/05/2013                     |                | Dx        | 2449             |     | Grpprac            | 3     | Uns Hypothyroidism                      |                             |             |     |                              | TEDN   | 242    |
| 384         | 703             | 09/05/2013                     |                | Dx        | 53081            |     | Grpprac            | 4     | Esophageal Reflux                       |                             |             |     |                              | TEDN   | 242    |
| 385         | 703             | 09/05/2013                     |                | Px        | 99214            |     | Grpprac            | 1     | Office Outpatient Visit 25 Minutes      |                             |             |     |                              | TEDN   | 242    |
| 386         | 706             | 09/08/2013                     |                | Rx        | 45802005505      |     |                    |       |                                         | Triamcinolone Acetonide     | 90          | 454 | Ointment(Gm)                 | PDTS   | 243    |
| 387         | 711             | 09/13/2013                     |                | Rx        | 00172635960      |     |                    |       |                                         | Tramadol Hcl-Acetaminophen  | 23          | 90  | Tablet                       | PDTS   | 244    |
| 388         | 711             | 09/13/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                         | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 245    |
| 389         | 712             | 09/14/2013                     |                | Rx        | 49884030402      |     |                    |       |                                         | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 246    |
| 390         | 713             | 09/15/2013                     |                | Rx        | 00173069600      |     |                    |       |                                         | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 247    |
| 391         | 721             | 09/23/2013                     |                | Rx        | 24987024257      |     |                    |       |                                         | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 248    |
| 392         | 725             | 09/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 249    |
| 393         | 725             | 09/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 249    |
| 394         | 726             | 09/28/2013                     |                | Rx        | 45802046564      |     |                    |       |                                         | Ketoconazole                | 30          | 240 | Shampoo                      | PDTS   | 250    |
| 395         | 726             | 09/28/2013                     |                | Rx        | 59762525004      |     |                    |       |                                         | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 251    |
| 396         | 726             | 09/28/2013                     |                | Rx        | 60429090260      |     |                    |       |                                         | Clobetasol Propionate       | 30          | 60  | Cream (Grams)                | PDTS   | 252    |
| 397         | 732             | 10/04/2013                     |                | Rx        | 00781282310      |     |                    |       |                                         | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 253    |
| 398         | 732             | 10/04/2013                     |                | Rx        | 00074455219      |     |                    |       |                                         | Synthroid                   | 90          | 90  | Tablet                       | PDTS   | 254    |
| 399         | 737             | 10/09/2013                     |                | Dx        | V679             |     | Fp                 | 1     | Uns Follow-Up Examination               |                             |             |     |                              | TEDN   | 255    |
| 400         | 737             | 10/09/2013                     |                | Px        | 77051            |     | Fp                 | 1     | Computer-Aided Detection Dx Mammography |                             |             |     |                              | TEDN   | 255    |
| 401         | 737             | 10/09/2013                     |                | Px        | G0206            |     | Fp                 | 1     | Diagnosticmammographydigital            |                             |             |     |                              | TEDN   | 256    |
| 402         | 742             | 10/14/2013                     |                | Rx        | 00186504085      |     |                    |       |                                         | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 257    |
| 403         | 755             | 10/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 258    |
| 404         | 755             | 10/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 258    |
| 405         | 764             | 11/05/2013                     |                | Rx        | 60429078910      |     |                    |       |                                         | Warfarin Sodium             | 90          | 65  | Tablet                       | PDTS   | 259    |
| 406         | 765             | 11/06/2013                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                           |                             |             |     |                              | TEDN   | 260    |
| 407         | 765             | 11/06/2013                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes      |                             |             |     |                              | TEDN   | 260    |
| 408         | 773             | 11/14/2013                     |                | Rx        | 49884030402      |     |                    |       |                                         | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 261    |
| 409         | 774             | 11/15/2013                     |                | Rx        | 00173069600      |     |                    |       |                                         | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 262    |
| 410         | 784             | 11/25/2013                     |                | Rx        | 24987024257      |     |                    |       |                                         | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 263    |
| 411         | 786             | 11/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 265    |
| 412         | 786             | 11/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 265    |
| 413         | 786             | 11/27/2013                     |                | Rx        | 59762525004      |     |                    |       |                                         | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 264    |
| 414         | 793             | 12/04/2013                     |                | Rx        | 00074455290      |     |                    |       |                                         | Synthroid                   | 90          | 90  | Tablet                       | PDTS   | 266    |
| 415         | 812             | 12/23/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                         | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 267    |
| 416         | 816             | 12/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 268    |
| 417         | 816             | 12/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 268    |
| 418         | 825             | 01/05/2014                     |                | Rx        | 60429078910      |     |                    |       |                                         | Warfarin Sodium             | 90          | 65  | Tablet                       | PDTS   | 269    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|---------------------------------------------|-----------------------------|-------------|-----|----------------------------------|--------|--------|
| 419         | 833             | 01/13/2014                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                         |                             |             |     |                                  | TEDN   | 271    |
| 420         | 833             | 01/13/2014                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis          |                             |             |     |                                  | TEDN   | 271    |
| 421         | 833             | 01/13/2014                     |                | Dx        | 4011             |     | Cardvasc           | 3     | Benign Essential Hypertension               |                             |             |     |                                  | TEDN   | 271    |
| 422         | 833             | 01/13/2014                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes          |                             |             |     |                                  | TEDN   | 271    |
| 423         | 833             | 01/13/2014                     |                | Rx        | 00781282310      |     |                    |       |                                             | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 270    |
| 424         | 834             | 01/14/2014                     |                | Rx        | 49884030402      |     |                    |       |                                             | Zafirlukast                 | 90          | 180 | Tablet                           | PDTS   | 272    |
| 425         | 835             | 01/15/2014                     |                | Rx        | 00173069600      |     |                    |       |                                             | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device     | PDTS   | 273    |
| 426         | 841             | 01/21/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                             | INDEX STUDY DRUG            | 30          |     | REFILL                           | PDTS   | 274    |
| 427         | 843             | 01/23/2014                     |                | Rx        | 00186504085      |     |                    |       |                                             | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 275    |
| 428         | 847             | 01/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                     |                             |             |     |                                  | TEDN   | 277    |
| 429         | 847             | 01/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                         |                             |             |     |                                  | TEDN   | 277    |
| 430         | 847             | 01/27/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                             | INDEX STUDY DRUG            | 90          |     | REFILL                           | PDTS   | 276    |
| 431         | 854             | 02/03/2014                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other            |                             |             |     |                                  | TEDN   | 279    |
| 432         | 854             | 02/03/2014                     |                | Px        | 36600            |     | Pulmo              | 1     | Arterial Puncture Withdrawal Blood Dx       |                             |             |     |                                  | TEDN   | 279    |
| 433         | 854             | 02/03/2014                     |                | Px        | 82375            |     | Pulmo              | 1     | Carboxyhemoglobin Quantitative              |                             |             |     |                                  | TEDN   | 280    |
| 434         | 854             | 02/03/2014                     |                | Px        | 82803            |     | Pulmo              | 1     | Blood Gases Any Combination Ph Pco2 Po2 C   |                             |             |     |                                  | TEDN   | 281    |
| 435         | 854             | 02/03/2014                     |                | Px        | 85018            |     | Pulmo              | 1     | Blood Count Hemoglobin                      |                             |             |     |                                  | TEDN   | 282    |
| 436         | 854             | 02/03/2014                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes          |                             |             |     |                                  | TEDN   | 283    |
| 437         | 854             | 02/03/2014                     |                | Px        | 71250            |     | Pulmo              | 1     | Ct Thorax W/O Contrast Material             |                             |             |     |                                  | TEDN   | 284    |
| 438         | 854             | 02/03/2014                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilata Rspse Spmtry Pre&post-Brncdilata |                             |             |     |                                  | TEDN   | 285    |
| 439         | 854             | 02/03/2014                     |                | Px        | 94200            |     | Pulmo              | 1     | Max Breathing Capacity Maximal Voluntary    |                             |             |     |                                  | TEDN   | 286    |
| 440         | 854             | 02/03/2014                     |                | Px        | 94726            |     | Pulmo              | 1     | Plethysmography Lung Volumes W/Wo Airway    |                             |             |     |                                  | TEDN   | 287    |
| 441         | 854             | 02/03/2014                     |                | Px        | 94729            |     | Pulmo              | 1     | Diffusing Capacity                          |                             |             |     |                                  | TEDN   | 288    |
| 442         | 854             | 02/03/2014                     |                | Dx        | 78605            |     | Grppract           | 1     | Shortness Breath                            |                             |             |     |                                  | TEDN   | 289    |
| 443         | 854             | 02/03/2014                     |                | Px        | 71250            |     | Grppract           | 1     | Ct Thorax W/O Contrast Material             |                             |             |     |                                  | TEDN   | 289    |
| 444         | 854             | 02/03/2014                     |                | Rx        | 00456080060      |     |                    |       |                                             | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 278    |
| 445         | 876             | 02/25/2014                     |                | Rx        | 59762525004      |     |                    |       |                                             | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                           | PDTS   | 290    |
| 446         | 878             | 02/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                     |                             |             |     |                                  | TEDN   | 291    |
| 447         | 878             | 02/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                         |                             |             |     |                                  | TEDN   | 291    |
| 448         | 882             | 03/03/2014                     |                | Rx        | 00456080060      |     |                    |       |                                             | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 292    |
| 449         | 884             | 03/05/2014                     |                | Dx        | 2449             |     | Grppract           | 1     | Uns Hypothyroidism                          |                             |             |     |                                  | TEDN   | 296    |
| 450         | 884             | 03/05/2014                     |                | Dx        | 27800            |     | Grppract           | 2     | Obesity Unspecified                         |                             |             |     |                                  | TEDN   | 296    |
| 451         | 884             | 03/05/2014                     |                | Dx        | 42731            |     | Grppract           | 3     | Atrial Fibrillation                         |                             |             |     |                                  | TEDN   | 296    |
| 452         | 884             | 03/05/2014                     |                | Dx        | 51631            |     | Grppract           | 4     | Idiopathic Pulmonary Fibrosis               |                             |             |     |                                  | TEDN   | 296    |
| 453         | 884             | 03/05/2014                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes          |                             |             |     |                                  | TEDN   | 296    |
| 454         | 884             | 03/05/2014                     |                | Rx        | 00781518110      |     |                    |       |                                             | Levothyroxine Sodium        | 90          | 90  | Tablet                           | PDTS   | 293    |
| 455         | 884             | 03/05/2014                     |                | Rx        | 00781282310      |     |                    |       |                                             | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 294    |
| 456         | 884             | 03/05/2014                     |                | Rx        | 65162062711      |     |                    |       |                                             | Tramadol Hcl                | 90          | 180 | Tablet                           | PDTS   | 295    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------------|--------|--------|
| 457         | 903             | 03/24/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 297    |
| 458         | 906             | 03/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                                  | TEDN   | 299    |
| 459         | 906             | 03/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                                  | TEDN   | 299    |
| 460         | 906             | 03/27/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast            | 90          | 180 | Tablet                           | PDTS   | 298    |
| 461         | 910             | 03/31/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                | 90          | 90  | Tablet                           | PDTS   | 300    |
| 462         | 910             | 03/31/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole           | 84          | 120 | Shampoo                          | PDTS   | 301    |
| 463         | 910             | 03/31/2014                     |                | Rx        | 50458065060      |     |                    |       |                                           | Ultracet               | 23          | 90  | Tablet                           | PDTS   | 302    |
| 464         | 919             | 04/09/2014                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                             |                        |             |     |                                  | TEDN   | 303    |
| 465         | 919             | 04/09/2014                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                  | TEDN   | 303    |
| 466         | 925             | 04/15/2014                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus          | 90          | 180 | Disk, With Inhalation Device     | PDTS   | 304    |
| 467         | 936             | 04/26/2014                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium        | 90          | 65  | Tablet                           | PDTS   | 305    |
| 468         | 944             | 05/04/2014                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 306    |
| 469         | 944             | 05/04/2014                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                           | PDTS   | 307    |
| 470         | 963             | 05/23/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 308    |
| 471         | 964             | 05/24/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair       | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 309    |
| 472         | 964             | 05/24/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                           | PDTS   | 310    |
| 473         | 966             | 05/26/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast            | 90          | 180 | Tablet                           | PDTS   | 311    |
| 474         | 968             | 05/28/2014                     |                | Rx        | 60429090260      |     |                    |       |                                           | Clobetasol Propionate  | 75          | 60  | Cream (Grams)                    | PDTS   | 312    |
| 475         | 991             | 06/20/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole           | 84          | 120 | Shampoo                          | PDTS   | 313    |
| 476         | 991             | 06/20/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                | 90          | 90  | Tablet                           | PDTS   | 314    |
| 477         | 1017            | 07/16/2014                     |                | Dx        | 78605            |     | Fp                 | 1     | Shortness Breath                          |                        |             |     |                                  | TEDN   | 316    |
| 478         | 1017            | 07/16/2014                     |                | Dx        | V5861            |     | Fp                 | 2     | Encounter Long Term Anticoagulant         |                        |             |     |                                  | TEDN   | 316    |
| 479         | 1017            | 07/16/2014                     |                | Px        | 71020            |     | Fp                 | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                  | TEDN   | 316    |
| 480         | 1017            | 07/16/2014                     |                | Px        | 85610            |     | Fp                 | 1     | Prothrombin Time                          |                        |             |     |                                  | TEDN   | 317    |
| 481         | 1017            | 07/16/2014                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                  | TEDN   | 320    |
| 482         | 1017            | 07/16/2014                     |                | Px        | 99283            |     | Grppract           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                                  | TEDN   | 321    |
| 483         | 1017            | 07/16/2014                     |                | Px        | 71020            |     | Grppract           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                  | TEDN   | 322    |
| 484         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 5781             |     |                    |       | 1 Blood In Stool                          |                        |             |     |                                  | TEDI   | 323    |
| 485         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 2800             |     |                    |       | 2 Iron Deficiency Anemia Blood Loss       |                        |             |     |                                  | TEDI   | 323    |
| 486         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 42731            |     |                    |       | 3 Atrial Fibrillation                     |                        |             |     |                                  | TEDI   | 323    |
| 487         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 79431            |     |                    |       | 4 Abnorm Electrocardiogram                |                        |             |     |                                  | TEDI   | 323    |
| 488         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 515              |     |                    |       | 5 Postinflammatory Pulmonary Fibrosis     |                        |             |     |                                  | TEDI   | 323    |
| 489         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 71590            |     |                    |       | 6 Osteoarthritis Unsp Site                |                        |             |     |                                  | TEDI   | 323    |
| 490         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 2449             |     |                    |       | 7 Uns Hypothyroidism                      |                        |             |     |                                  | TEDI   | 323    |
| 491         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 30000            |     |                    |       | 8 Anxiety State Unspecified               |                        |             |     |                                  | TEDI   | 323    |
| 492         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | V5861            |     |                    |       | 9 Encounter Long Term Anticoagulant       |                        |             |     |                                  | TEDI   | 323    |
| 493         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | V4586            |     |                    |       | 10 Bariatric Surgery Status               |                        |             |     |                                  | TEDI   | 323    |
| 494         | 1017            | 07/16/2014                     | 07/19/2014     | Px        | 4513             |     |                    |       | 1 Sm Bowel Endoscopy Other Spec           |                        |             |     |                                  | TEDI   | 323    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 495         | 1017            | 07/16/2014                     | 07/19/2014     | Px        | 9904  |      |                    | 2     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 323    |
| 496         | 1017            | 07/16/2014                     |                | Dx        | 79431 | Inpt | Cardvasc           | 1     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 315    |
| 497         | 1017            | 07/16/2014                     |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 315    |
| 498         | 1017            | 07/16/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 318    |
| 499         | 1017            | 07/16/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 318    |
| 500         | 1017            | 07/16/2014                     |                | Px        | 99221 | Inpt | Gastro             | 1     | Initial Hospital Care/Day 30 Minutes      |                        |             |     |                  | TEDN   | 318    |
| 501         | 1017            | 07/16/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 319    |
| 502         | 1017            | 07/16/2014                     |                | Dx        | 2800  | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                        |             |     |                  | TEDN   | 319    |
| 503         | 1017            | 07/16/2014                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 319    |
| 504         | 1017            | 07/16/2014                     |                | Dx        | 79431 | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 319    |
| 505         | 1017            | 07/16/2014                     |                | Dx        | 515   | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                        |             |     |                  | TEDN   | 319    |
| 506         | 1017            | 07/16/2014                     |                | Dx        | 71590 | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                        |             |     |                  | TEDN   | 319    |
| 507         | 1017            | 07/16/2014                     |                | Dx        | 2449  | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 319    |
| 508         | 1017            | 07/16/2014                     |                | Dx        | 30000 | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                        |             |     |                  | TEDN   | 319    |
| 509         | 1017            | 07/16/2014                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 319    |
| 510         | 1018            | 07/17/2014                     |                | Dx        | 78605 | Inpt | Cardvasc           | 1     | Shortness Breath                          |                        |             |     |                  | TEDN   | 324    |
| 511         | 1018            | 07/17/2014                     |                | Dx        | 79431 | Inpt | Cardvasc           | 2     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 324    |
| 512         | 1018            | 07/17/2014                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 324    |
| 513         | 1018            | 07/17/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 325    |
| 514         | 1018            | 07/17/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 325    |
| 515         | 1018            | 07/17/2014                     |                | Px        | 43235 | Inpt | Gastro             | 1     | Upper Gi Ndsc Dx W/Wo Collection Specimen |                        |             |     |                  | TEDN   | 325    |
| 516         | 1018            | 07/17/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 326    |
| 517         | 1018            | 07/17/2014                     |                | Dx        | 2800  | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                        |             |     |                  | TEDN   | 326    |
| 518         | 1018            | 07/17/2014                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 326    |
| 519         | 1018            | 07/17/2014                     |                | Dx        | 79431 | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 326    |
| 520         | 1018            | 07/17/2014                     |                | Dx        | 515   | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                        |             |     |                  | TEDN   | 326    |
| 521         | 1018            | 07/17/2014                     |                | Dx        | 71590 | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                        |             |     |                  | TEDN   | 326    |
| 522         | 1018            | 07/17/2014                     |                | Dx        | 2449  | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 326    |
| 523         | 1018            | 07/17/2014                     |                | Dx        | 30000 | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                        |             |     |                  | TEDN   | 326    |
| 524         | 1018            | 07/17/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 326    |
| 525         | 1018            | 07/17/2014                     |                | Px        | 74150 | Inpt | Grppract           | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 327    |
| 526         | 1019            | 07/18/2014                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 328    |
| 527         | 1019            | 07/18/2014                     |                | Dx        | 5789  | Inpt | Cardvasc           | 2     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 328    |
| 528         | 1019            | 07/18/2014                     |                | Px        | 99232 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 328    |
| 529         | 1019            | 07/18/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 329    |
| 530         | 1019            | 07/18/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 329    |
| 531         | 1019            | 07/18/2014                     |                | Px        | 99231 | Inpt | Gastro             | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 329    |
| 532         | 1019            | 07/18/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 330    |

Patient ID: ILD-0088

Age: 71 Gender: F Indexdate: 10/03/2011 Event Date: 07/16/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description      | Days Supply | QTY | Drug Formulation           | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|----------------------------|--------|--------|
| 533         | 1019            | 07/18/2014                     |                | Dx        | 2800        | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                             |             |     |                            | TEDN   | 330    |
| 534         | 1019            | 07/18/2014                     |                | Dx        | 42731       | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 330    |
| 535         | 1019            | 07/18/2014                     |                | Dx        | 79431       | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                             |             |     |                            | TEDN   | 330    |
| 536         | 1019            | 07/18/2014                     |                | Dx        | 515         | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                             |             |     |                            | TEDN   | 330    |
| 537         | 1019            | 07/18/2014                     |                | Dx        | 71590       | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                             |             |     |                            | TEDN   | 330    |
| 538         | 1019            | 07/18/2014                     |                | Dx        | 2449        | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                             |             |     |                            | TEDN   | 330    |
| 539         | 1019            | 07/18/2014                     |                | Dx        | 30000       | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                             |             |     |                            | TEDN   | 330    |
| 540         | 1019            | 07/18/2014                     |                | Px        | 99232       | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                             |             |     |                            | TEDN   | 330    |
| 542         | 1020            | 07/19/2014                     |                | Dx        | 5781        | Inpt | Grppract           | 1     | Blood In Stool                            |                             |             |     |                            | TEDN   | 332    |
| 543         | 1020            | 07/19/2014                     |                | Dx        | 2800        | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                             |             |     |                            | TEDN   | 332    |
| 544         | 1020            | 07/19/2014                     |                | Dx        | 42731       | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 332    |
| 545         | 1020            | 07/19/2014                     |                | Dx        | 79431       | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                             |             |     |                            | TEDN   | 332    |
| 546         | 1020            | 07/19/2014                     |                | Dx        | 515         | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                             |             |     |                            | TEDN   | 332    |
| 547         | 1020            | 07/19/2014                     |                | Dx        | 71590       | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                             |             |     |                            | TEDN   | 332    |
| 548         | 1020            | 07/19/2014                     |                | Dx        | 2449        | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                             |             |     |                            | TEDN   | 332    |
| 549         | 1020            | 07/19/2014                     |                | Dx        | 30000       | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                             |             |     |                            | TEDN   | 332    |
| 550         | 1020            | 07/19/2014                     |                | Px        | 99238       | Inpt | Grppract           | 1     | Hospital Discharge Day Management 30 Min/ |                             |             |     |                            | TEDN   | 332    |
| 541         | 1020            | 07/19/2014                     |                | Rx        | 53746027205 |      |                    |       |                                           | Sulfamethoxazole-Trimethopr | 3           | 6   | Tablet                     | PDTS   | 331    |
| 551         | 1022            | 07/21/2014                     |                | Rx        | 00781518110 |      |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                     | PDTS   | 333    |
| 552         | 1024            | 07/23/2014                     |                | Rx        | 60429090260 |      |                    |       |                                           | Clobetasol Propionate       | 90          | 60  | Cream (Grams)              | PDTS   | 334    |
| 553         | 1029            | 07/28/2014                     |                | Dx        | 2809        |      | Gastro             | 1     | Uns Iron Deficiency Anemia                |                             |             |     |                            | TEDN   | 335    |
| 554         | 1029            | 07/28/2014                     |                | Dx        | 5781        |      | Gastro             | 2     | Blood In Stool                            |                             |             |     |                            | TEDN   | 335    |
| 555         | 1029            | 07/28/2014                     |                | Px        | 99212       |      | Gastro             | 1     | Office Outpatient Visit 10 Minutes        |                             |             |     |                            | TEDN   | 335    |
| 556         | 1031            | 07/30/2014                     |                | Dx        | 4011        |      | Cardvasc           | 1     | Benign Essential Hypertension             |                             |             |     |                            | TEDN   | 336    |
| 557         | 1031            | 07/30/2014                     |                | Dx        | 42731       |      | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 336    |
| 558         | 1031            | 07/30/2014                     |                | Dx        | 28659       |      | Cardvasc           | 3     | Ot Intrin Circ Anticoag Hemorr Dis        |                             |             |     |                            | TEDN   | 336    |
| 559         | 1031            | 07/30/2014                     |                | Px        | 99213       |      | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                            | TEDN   | 336    |
| 560         | 1034            | 08/02/2014                     |                | Rx        | 00781282310 |      |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 337    |
| 561         | 1037            | 08/05/2014                     |                | Dx        | 5789        |      | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                            | TEDN   | 338    |
| 562         | 1037            | 08/05/2014                     |                | Dx        | 51889       |      | Grppract           | 2     | Oth Diseases Lung Other                   |                             |             |     |                            | TEDN   | 338    |
| 563         | 1037            | 08/05/2014                     |                | Dx        | 4279        |      | Grppract           | 3     | Uns Cardiac Dysrhythmia                   |                             |             |     |                            | TEDN   | 338    |
| 564         | 1037            | 08/05/2014                     |                | Dx        | 5990        |      | Grppract           | 4     | Urinary Tract Infection Unspec            |                             |             |     |                            | TEDN   | 338    |
| 565         | 1037            | 08/05/2014                     |                | Px        | 99213       |      | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                            | TEDN   | 338    |
| 566         | 1040            | 08/08/2014                     |                | Rx        | 47781030301 |      |                    |       |                                           | Nitrofurantoin Mono-Macro   | 7           | 14  | Capsule (Hard, Soft, Etc.) | PDTS   | 339    |
| 567         | 1043            | 08/11/2014                     |                | Dx        | 42731       |      | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 340    |
| 568         | 1043            | 08/11/2014                     |                | Dx        | 78609       |      | Cardvasc           | 2     | Respiratory Abnormality Ot                |                             |             |     |                            | TEDN   | 340    |
| 569         | 1043            | 08/11/2014                     |                | Dx        | 4011        |      | Cardvasc           | 3     | Benign Essential Hypertension             |                             |             |     |                            | TEDN   | 340    |
| 570         | 1043            | 08/11/2014                     |                | Px        | 78452       |      | Cardvasc           | 1     | Myocardial Spect Multiple Studies         |                             |             |     |                            | TEDN   | 340    |

Patient ID: ILD-0088

Age: 71 Gender: F Indexdate: 10/03/2011 Event Date: 07/16/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code             | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description      | Days Supply | QTY | Drug Formulation                 | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|----------------------------------|--------|--------|
| 571         | 1043            | 08/11/2014                     |                | Px        | 93015            |     | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Phys Si& |                             |             |     |                                  | TEDN   | 341    |
| 572         | 1043            | 08/11/2014                     |                | Px        | A9500            |     | Cardvasc           | 1     | Tc99m Sestamibi                           |                             |             |     |                                  | TEDN   | 342    |
| 573         | 1043            | 08/11/2014                     |                | Px        | J2785            |     | Cardvasc           | 1     | Regadenoson Injection                     |                             |             |     |                                  | TEDN   | 343    |
| 574         | 1046            | 08/14/2014                     |                | Rx        | 53746017801      |     |                    |       |                                           | Metformin Hcl Er            | 30          | 30  | Tablet, SR 24hr                  | PDTS   | 344    |
| 575         | 1050            | 08/18/2014                     |                | Rx        | 42291061010      |     |                    |       |                                           | Metformin Hcl Er            | 90          | 90  | Tablet, SR 24hr                  | PDTS   | 345    |
| 576         | 1053            | 08/21/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 346    |
| 577         | 1053            | 08/21/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                           | PDTS   | 347    |
| 578         | 1056            | 08/24/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                           | PDTS   | 348    |
| 579         | 1061            | 08/29/2014                     |                | Rx        | 00310014111      |     |                    |       |                                           | Zestoretic                  | 90          | 90  | Tablet                           | PDTS   | 349    |
| 580         | 1061            | 08/29/2014                     |                | Rx        | 68180051801      |     |                    |       |                                           | Lisinopril-Hydrochlorothiaz | 14          | 14  | Tablet                           | PDTS   | 350    |
| 581         | 1065            | 09/02/2014                     |                | Dx        | 79029            |     | Grppract           | 1     | Other Abnormal Glucose                    |                             |             |     |                                  | TEDN   | 352    |
| 582         | 1065            | 09/02/2014                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 352    |
| 583         | 1065            | 09/02/2014                     |                | Rx        | 53746061701      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 8           | 30  | Tablet                           | PDTS   | 351    |
| 584         | 1072            | 09/09/2014                     |                | Rx        | 50458065060      |     |                    |       |                                           | Ultracet                    | 90          | 360 | Tablet                           | PDTS   | 353    |
| 585         | 1075            | 09/12/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole                | 84          | 120 | Shampoo                          | PDTS   | 354    |
| 586         | 1078            | 09/15/2014                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                                  | TEDN   | 355    |
| 587         | 1078            | 09/15/2014                     |                | Dx        | 2859             |     | Cardvasc           | 2     | Anemia Unspecified                        |                             |             |     |                                  | TEDN   | 355    |
| 588         | 1078            | 09/15/2014                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 355    |
| 589         | 1079            | 09/16/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 356    |
| 590         | 1093            | 09/30/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                     | 90          | 90  | Tablet                           | PDTS   | 357    |

End of Profile

## **APPENDIX 2. EPIDEMIOLOGY STEERING COMMITTEE & INDEPENDENT ADJUDICATION PANELS**

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## **Study Committees**

This study included an Epidemiology Steering Committee for monitoring of study progress as well as an independent adjudication panel for each of the two outcome events. Each committee had its own charter with written roles and responsibilities. Written minutes were kept of all committee meetings.

### **A. EPIDEMIOLOGY STEERING COMMITTEE**

An external Epidemiology Steering Committee (ESC) was convened to provide scientific oversight and advice on the Epidemiologic Study Protocol. Degge's tasks associated with the ESC included identification of qualified members, administrative management, Charter development and approval, and Committee meeting management. The ESC met a total of seven (7) times; once in November 2011; once in November 2012; four (4) times in 2013; once in 2014; and once in 2016.

### **Administrative Management of Epidemiology Steering Committee**

Primary administrative management of the ESC included contracting with experts and facilitating arrangements for travel and accommodations related to committee meetings. Degge organized ESC meetings, provided Agenda and discussion items, distributed meeting materials to all members prior to meetings, and recorded, transcribed and disseminated meeting minutes to all participants.

### **Epidemiology Steering Committee Members**

The ESC consisted of seven experts in their fields, and included hepatologists, epidemiologists, statisticians, regulatory drug safety experts with experience in liver injury, and cardiologists. Panel members served for the term of the study, which was approximately five years. The ESC members were:

Judith K Jones, MD, PhD, FISPE, Chair  
The Degge Group, Ltd., Fairfax, Virginia

Rhonda L Bohn, ScD, MPH, FISPE, Co-Chair  
Rhonda L Bohn, LLC, Boston, Massachusetts

(Jean) Toby Barbey, MD, Cardiologist  
Social Scientific Sciences, Silver Spring, Maryland

(John) Michael Gaziano, MD, MPH, Cardiologist/Epidemiologist  
Brigham & Women's Hospital, Boston, Massachusetts  
[NOTE: Resigned as of 25 August 2014. A replacement was not identified.]



James H. Lewis, MD, Hepatologist  
Georgetown University, Washington, District of Columbia

Captain Sally Tamayo, MD, Cardiologist,  
Navy Medical Center, US Department of Defense, Portsmouth, Virginia

Susan T. Sacks, PhD, FISPE, Epidemiologist/Statistician  
Independent, Scottsdale, Arizona

## **Epidemiology Steering Committee Charter**

The Epidemiology Steering Committee Charter is provided below.

The Charter was initially approved on November 10, 2011 by the ESC. It was later revised to define the term “quorum” in [Section IX Voting](#). New wording appears with yellow highlighted text.

Decisions will be based upon a simple majority (**at least 3 out of 5**) or unanimity. When meeting by teleconference, members not physically present will be required to e-mail their decision on votes posed during that teleconference to the Chair and Co-Chair. The Chair and Co-Chair shall be non-voting members of the Committee.

## **B. INDEPENDENT ADJUDICATION PANELS (IAPS)**

Two separate IAPs were convened, one for each outcome event;

- Independent Adjudication Panel – Serious Liver Disease/Injury (IAP-SLD); and
- Independent Adjudication Panel – Interstitial Lung Disease (IAP-ILD).

## **Administrative Management of the IAPs**

Degge coordinated the outcome event review for the IAPs and convened all Adjudication Review Meetings to adjudicate differences in individual members’ outcome event judgments. Dr. Jones chaired the meetings with Earl Goehring and as needed provided technical details relating to the databases or the committee’s responsibilities, but did not provide additional clinical opinions on the cases. Degge also recorded meeting minutes and disseminated summaries of the meeting minutes to all participants.

## **IAP Members**

Each IAP, one devoted to serious liver disease (SLD) outcomes and the other to interstitial lung disease (ILD) outcomes, had three members. The goal was to have at least two specialists in each IAP representing their respective therapeutic areas (i.e., liver Injury or pulmonary disease). Members served for the term of the study.

**IAP-SLD members included:**

- Willis C. Maddrey, MD, *Assistant to the President*, UT Southwestern Medical Center, Dallas, Texas,
- Natalie GB Murray, MD, *Medical Director - Liver Transplantation*, Baylor All Saints Medical Center, Texas, Fort Worth, Texas,
- Mark Russo, MD, MPH, *Medical Director of Liver Transplantation, Chief, Division of Hepatology*, Carolinas Medical Center, Charlotte, North Carolina.

**IAP-ILD members included:**

- Kevin R. Flaherty, MD, MS, *Professor of Internal Medicine*, University of Michigan Health System, Ann Harbor, Michigan,
- David J. Lederer, MD, MS, *Associate Medical Director, NYP/Columbia Lung Transplant Program*, Columbia University Medical Center, New York, New York,
- Ganesh Raghu, MD, *Director, Center of Interstitial Lung Disease*, University of Washington Medical Center, Seattle, Washington.

## **IAP Charters and Procedures**

Each IAP had a Charter describing the Panel's role and responsibilities, the adjudication process, and voting rules. A critical feature of the charters was the requirement that each member evaluate the cases **individually** without consultation with other IAP members. Differences in judgements were adjudicated in joint meetings.

The clinical profiles to be reviewed were based upon date-specific electronic medical record summaries of patients' medical care, institutionalizations, physician visits, procedures and pharmaceuticals prescribed. (See example, below.) These were not medical "chart" reviews, and most of the panel members were not accustomed to reviewing clinical materials formatted this way. The investigators believed it was very important that the adjudicators clearly understood how to interpret the profile data. Practice sessions were therefore conducted for each panel in order to orient the members to reading and reviewing the medical history for each patient.

The Charters and Procedures for each Panel are provided below, as well as a copy of the individual review forms for each outcome event.

## **C. EPIDEMIOLOGY STEERING COMMITTEE - CHARTER**

### **EPIDEMIOLOGY STEERING COMMITTEE CHARTER**

**For  
Sanofi-Aventis -  
Dronedarone Surveillance Study**

**Charter Drafted:** October 26, 2011

**Charter Reviewed:** November 10, 2011

**Charter Approved:** November 10, 2011

**Revised and Approved:** November 8, 2012

# EPIDEMIOLOGY STEERING COMMITTEE CHARTER

## For Sanofi-aventis - Dronedarone Surveillance Program

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## **Epidemiology Steering Committee CHARTER**

### **For Sanofi-aventis - Dronedarone Surveillance Program**

**Initial Review:** November 10, 2011

**Approved:** November 8, 2012

## **I. INTRODUCTION**

Dronedarone (Multaq®) is an anti-arrhythmic drug with effects from all four classes of the Vaughan Williams' classification indicated for treatment of patients with non-permanent atrial fibrillation. The recommended dose is 400 mg twice daily in adults. Dronedarone was initially authorized on July 20, 2009 in the United States. It is currently marketed in 27 countries in the Americas, Europe, and Asia. The calculated cumulative number of tablets distributed globally through September 2010 represents a total exposure of 79,503 patient-years.<sup>1</sup>

Two recent case reports that resulted in transplantation have necessitated the development of epidemiologic studies to examine dronedarone use and the occurrence of serious liver related injury.

To accomplish this goal, sanofi-aventis wishes to develop a comprehensive strategy for surveillance of a large proportion of the US population exposed to dronedarone, to determine the feasibility of detecting, characterizing, and quantifying the occurrence of serious liver injury associated with its use. In order to accomplish this, The Degge Group Ltd. (Degge) has proposed a multi-dimensional program which utilizes external data sources to meet the Company's objectives.

## **II. PURPOSE**

The Epidemiology Steering Committee (ESC) shall be responsible for overseeing the scientific integrity, validity of the study protocol, assessment of study quality and conduct, as well as, the scientific quality of interim reports and the final study report.

## **III. COMPOSITION OF THE COMMITTEE**

The ESC consists of five individuals who have expertise in one or more of the following areas: hepatology, cardiology, liver-associated injury, epidemiology, biostatistics, and regulatory drug

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<sup>1</sup> Sanofi-Aventis. Dronedarone – Summary of Hepatic Safety Data Report, page 4, December 10, 2010.

safety. In addition, there will be a Committee Chair and Co-Chair.

The members include:

1. Judith K. Jones, MD, PhD, FISPE – Committee Chair (Non-voting member)
2. Rhonda L. Bohn, MPH, ScD, FISPE – Committee Co-Chair (Non-voting member)
3. (Jean) Tobey Barbey, MD
4. (John) Michael Gaziano, MD, MPH
5. James H. Lewis, MD
6. Commander Sally Tamayo, MD
7. Susan T. Sacks, PhD, FISPE

Degge will coordinate all Committee meetings and maintain minutes. Curriculum vitae of the members are attached. Earl Goehring, (Managing Director, The Degge Group, and Ltd.) will be charged with operational related items for the Steering Committee.

#### **IV. MEMBERSHIP TERM**

Committee members shall serve for the term of the study, which is estimated to last for approximately 4 years. If a member resigns or is otherwise unable to serve, a substitute will be selected in mutual agreement between the Chair and the sponsor. This substitute shall have the same duties and responsibilities as the other members.

#### **V. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST**

Members of the ESC will be individually responsible for disclosing to the Chair/Co-Chair, other members, the sponsor and – upon request – to authorities any pharmaceutical or medical device companies in which they hold a financial interest or consulting agreement that may represent a conflict for performance on this Board.

The ESC will be responsible for deciding whether such financial interests may reasonably be considered to have a potential impact on the Member's objectivity. If such a decision is made by a majority vote of the Committee members, the member must either divest themselves of those interests or resign from the Committee.

Members will be responsible for advising the Committee of any changes in their financial interests that may create a conflict of interest; these members will be asked to resign from the Committee or to divest themselves of those relationships/interests.

#### **VI. DATA PROVIDED FOR REVIEW**

Degge prepared and forwarded materials for the ESC to review. For the initial orientation meeting, the Committee members received the dronedarone package insert, the Dronedarone Surveillance Protocol, a draft copy of Charter, and additional background materials relevant to the study.

For subsequent meetings, the Chair/Co-Chair and Degge staff assured that the members have the appropriate materials at least one week prior to any planned meeting. The Chair will make the determination which materials were appropriate and needed to be provided.

## **VII. DATA REVIEW AND EVALUATION**

The information and data provided to the ESC was reviewed at Committee meetings. Since all data collected in this study are open, there is no need for closed sessions of the ESC. All meetings were held as 'open' meetings that sponsor representatives may attend.

## **VIII. MEETINGS**

An initial organizational meeting was convened in person at the offices of The Degge Group, Ltd. located in Arlington, Virginia on November 10, 2011. Sanofi-Aventis representatives will provide participants with an overview of the dronedarone history and current overall program. Further orientation was presented by the Chair/Co-Chair.

A schedule for further meetings and venue (face-to-face, teleconference) was established by the ESC in collaboration with the sponsor, bearing in mind the periodicity of interim study reports and potential authority requests that will require input and review by the ESC.

Committee members were given the opportunity to familiarize themselves with all aspects of the observational study, to provide scientific or methodological advice, and address any questions or concerns pertaining to the Committee. A briefing binder of all relevant materials was provided to Committee members to facilitate the Committee's deliberations for subsequent meetings.

## **IX. VOTING**

All members are required to be present in person or by telephone for a quorum, if a vote is to be cast. Decisions were based upon a simple majority (at least 3 out of 5) or unanimity. When meeting by teleconference, members not physically present will be required to e-mail their decision on votes posed during that teleconference to the Chair and Co-Chair. The Chair and Co-Chair were non-voting members of the Committee.

## **X. ROLE OF THE EPIDEMIOLOGY STEERING COMMITTEE**

The Epidemiology Steering Committee was charged with providing advice on the conduct and analysis of the Dronedarone Surveillance Study. While it is the prerogative of Sanofi-Aventis as the sponsor to change the protocol or to discontinue the study, Sanofi-Aventis will consult with the ESC for such changes.

## **XI. MINUTES**

The Chair and Co-Chair shall prepare minutes for the Committee meetings. The Chair/Co-Chair shall distribute the minutes to other Committee members and Sanofi-Aventis.

representatives within two weeks of the meeting. All minutes were reviewed and approved by the Committee to reflect the panel's opinions and conclusions regarding all reviewed issues.

## **XII. CONFIDENTIALITY**

All materials and information relating to this Committee shall be strictly confidential pursuant to Degge's confidentiality agreement.

## **XIII. PUBLICATION POLICY**

Epidemiology Steering Committee (ESC) members may author or contribute to a publication resulting from the surveillance study. The International Board of Medical Journal Editors (ICMJE) considers an "author" to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.

The ICMJE has recommended the following criteria for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors may ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged.

*Source: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship*



**D. IAP: SERIOUS LIVER INJURY / DISEASE (SLD) - CHARTER**

**Independent Adjudication Panel –  
Serious Liver Injury / Disease (SLD)  
For**

**Serious Liver Injury And Interstitial Lung Disease Occurrences  
In Patients Diagnosed With Atrial Fibrillation Treated With  
Selected Anti-Arrhythmics**

**(DRONE\_C\_05917)**

**CHARTER**

February 20, 2015

# **Independent Adjudication Panel – Serious Liver Injury / Disease CHARTER**

**For**

**Serious Liver Injury/Disease And Interstitial Lung Disease Occurrences In  
Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-  
Arrhythmics**

**(DRONE\_C\_05917)**

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## **Independent Adjudication Panel – Serious Liver Injury/Disease CHARTER**

For

**Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients  
Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics**

**(DRONE\_C\_05917)**

### **I. INTRODUCTION**

Dronedaron (Multaq®) is an anti-arrhythmic drug with effects on all four classes of the Vaughan Williams' classification utilized for treatment of patients with non-permanent Atrial Fibrillation (AF). Dronedaron was initially authorized on 1 July 2009 in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing pharmacovigilance data of spontaneous reports indicate safety signals related to interstitial lung disease (ILD), and serious liver injury /disease (SLD). In order to examine these associations in the real-world setting, where dronedaron is approved for non-permanent AF/AFL, Sanofi requested a retrospective cohort study examining the association between dronedaron and comparator anti-arrhythmic drugs and these subsequent events among adults.

The Degge Group, Ltd., a drug safety consulting firm, has been retained to help in the original study design and coordination of an epidemiologic study titled, "*Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics (DRONE\_C\_05917)*". Degge is also charged with providing oversight management and content support of the Epidemiology Steering Committee and the Independent Adjudication Panels (IAP), and to contribute to the final analysis of the results.

### **II. COMPOSITION OF THE ADJUDICATION PANEL**

The IAP consists of three individuals who bring 3+ years of experience and expertise relating to severe liver injury in patients, have the expertise to review individual profiles from electronic medical records and/or administrative claims data, and general clinical management of patients with liver injury.

The Panel includes:

- Judith K. Jones, MD, PhD, FISPE, President & CEO, The Degge Group, Ltd., Fairfax, VA (Panel Chair)
- Willis C. Maddrey, MD, University of Texas – Southwestern Medical Center,
- Natalie GB Murray, MD, Baylor All Saints Medical Center,
- Mark W. Russo, MD, MPH, Carolinas Medical Center.

Dr. Judith K. Jones will Chair the Panel and the meetings and with assistance of Degge staff, maintain minutes of the meetings. The curriculum vitae of the Panelists will be attached.

### **III. MEMBERSHIP TERM**

Panel members are to serve for the term of the study, which is estimated to last for approximately two years. If a Panel member is unable to serve, the Panel Chairperson shall select a substitute. This substitute shall have the same duties and responsibilities as the other members.

### **IV. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST**

Members of the IAP represent that they have disclosed to the Panel Chair any and all conflicts of interest that would prevent their participation and performance on the Panel.

Members will be responsible for advising the Panel of any changes in their financial interests that may create a conflict of interest. Members who develop financial relationships that might be perceived to result in conflicts of interests or to impair objectivity will be asked to resign from the Panel or to divest themselves of those relationships/interests. If they resign, the Chair shall select a replacement to serve on the IAP.

### **V. DATA PROVIDED FOR REVIEW**

Degge will prepare and forward materials for the IAP to review. For the initial orientation meeting, the Panel members will receive the package insert for each of the study drugs, the Study Protocol, and additional background material relevant to this study. For subsequent meetings, the Chair and Degge staff will assure that Panel members have the appropriate materials at least one week prior to the planned meetings.

### **VI. DATA REVIEW AND EVALUATION**

The information and data provided to the IAP will be reviewed independently by each member. Individual patient profile information may be discussed at closed Panel meetings. Closed sessions will comprise only the Panel members and Degge administrative staff. The Panel meetings may consist of open sessions where employees of Sanofi and HealthCore may be involved to provide project overviews and status updates. Individual patient profile information will not be discussed in open sessions.

### **VII. MEETINGS**

An initial organizational meeting will be convened in person at Degge's office in Fairfax, Virginia. Representatives of Sanofi will provide participants with an overview of the Dronedarone history and current overall program. The Study Protocol will be presented by Degge.

Panel members will be given the opportunity to familiarize themselves with all aspects of the observational study protocol and may ask any questions or concerns. A briefing binder of selected materials will be provided to Panel members to facilitate the discussions.

### **VIII.VOTING**

Since the Panel is small, all Panel members are required to be present in person or by telephone for a quorum, if a vote is to be cast. Decisions are based upon unanimous

agreement. The Chairperson will not vote. There will be discussion only if a decision is not unanimous and decision is based upon a simple majority.

## **IX. DECISIONS OF THE INDEPENDENT ADJUDICATION PANEL**

The IAP is charged with determining whether liver injury/disease outcome events are true cases as defined in the Epidemiology Study Protocol. The specific procedures for adjudication are in **Attachment 1**.

## **X. MEETING MINUTES**

The Chair shall prepare minutes from the Panel meetings. To assist the Chair in this responsibility, a Degge staff member shall be designated by the Chair to take minutes during each meeting. The Chair shall edit these minutes and distribute to the other Panel members, Sanofi, and data partners within two weeks of the meeting. The minutes shall be approved by the Panel by email as well as during the following meeting to accurately reflect the Panel's opinions and conclusions regarding all reviewed issues.

## **XI. CONFIDENTIALITY**

All Panel members have agreed to and are bound by Confidentiality Agreements. All materials and information relating to this Panel shall be maintained strictly confidential pursuant to Degge's confidentiality agreement.

## **XII. SUNSHINE ACT REPORTING**

Federal law requires that pharmaceutical companies fully capture all transfers of value made to any covered US licensed health care provider (physicians, nurse practitioners, nurses, hospitals, clinics, PBMs, health insurance carriers, etc.). As such, Degge is responsible for reporting to Sanofi any and all financial payments made to Panel members, who are active licensed physicians, for their participation while serving on the Panel.

## ATTACHMENT 1. PATIENT PROFILE REVIEW & ADJUDICATION PROCEDURES

### Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics (DRONE\_C\_05917)

#### Independent Adjudication Panel

The Independent Adjudication Panel has been created to review and adjudicate potential cases identified in each of the study databases as described in the current *Study Protocol*.

#### I. Potential Case Identification

##### A. Review Cases identified via Selection Algorithm

A selection algorithm was developed to identify potential outcome events in patients that are in the cohort study conducted in the US DoD and HealthCore Integrated Research Database (HIRD™) databases. Patient Profiles of the patients with potential outcome events will be provided to the IAP for outcome event adjudication and determination as defined in the study protocol.

##### B. Patient Profile Creation

Specifications on the layout of the Patient Profile will be provided to the groups involved in generating the profiles.

##### C. Receipt of Patient Profiles from Data Vendor

1. Patient profiles of potential cases will be provided to a Degge staff person in electronic format that is password protected.
2. The profile IDs and adjudicated status will be recorded in a tracking spreadsheet.

##### D. Storage of Patient Profiles

The creation and distribution of patient profile data from the US DoD and HIRD will adhere to Degge's Data Protection Policy, see **Attachment 2**. Copies are not provided to representatives of the sponsor, Sanofi, at any time.

##### E. IAP Review

The Panel, including the Chair, will be blinded to:

1. Study database, and
2. Study drugs of interest

## II. Patient Profile Review

### A. Initial Review

1. Staff Screening/Verification – Degge staff will review all profiles to:
  - a. Record potential case information in outcome event tracking spreadsheet,
  - b. Assure study database name and study drugs of interest have been blinded,
  - c. Determine that a study outcome is present,
  - d. Attach corresponding event review form with event definitions.

### B. Adjudication / Reconciliation Review Process

1. All Panel members will familiarize themselves with the Protocol and the outcome event definitions to facilitate decisions.
2. Assignment of Cases. Depending on the number of potential cases to review, the IAP may meet face-to-face for 1 or 2 full days, or review password protected electronic files containing a large number of cases.
3. Each Panel member will initially review potential cases independently:
  - a. To determine based upon the characteristics and timing relative to the blinded study drug's exposure, whether the designated liver event suggests a serious liver injury/disease outcome event as defined in the Study Protocol, and based on good clinical judgment. Event determination includes assignment as either:
    - “**Yes**” – the information provided meets the outcome event criteria,
    - “**No**” – the information provided does not meet the outcome event criteria, or
    - “**Indeterminate**” – the information provided does not meet the outcome event criteria, as defined in the study protocol, but the clinical picture suggests an outcome event.
4. Outcome Event Tabulation and Reconciliation:
  - a. Reviewer decisions will be tabulated for each case.
    - i. Cases with unanimous Reviewer agreement will have that determination assigned in the database. No further discussion will be needed.
    - ii. If disagreement between the Panel members exists, the patient profile will be discussed in a formal meeting where all three Panel members and the Chair are present. The Chair will lead the discussion. Panel members will each present reasoning for their decision, followed by a final vote. If a consensus is reached, that determination will be assigned in the database; else the event will be assigned as “Indeterminate”.

### C. Reporting Outcome Events back to Study Databases

Upon the IAP's completed review of all potential events, the final results (event determination) will be provided back to the respective study databases to continue the study analyses.

More detailed procedures and forms to facilitate decision-making may be developed in the first reviews of actual cases.

## ATTACHMENT 2. DATA PROTECTION POLICY – PROJECT SPECIFIC

**Project:** Sanofi: Dronedarone Surveillance Study      **Project #:** 0204-110  
**Location:** The Degge Group, Ltd. office only  
**Required:** Restricted Access – Fixed Storage Media  
**PM:** Earl Goehring, Managing Director, Research

### I. Restricted Access – Fixed Storage Media

1. Physical access to profile data will be restricted to authorized persons by the following:
  - a. All non-removable or (re-)writable storage media with profile data will be configured with file systems that support access control. These include:
    - i. Password protection of all devices storing profile data.
    - ii. Data files will have robust security settings in place managed by Earl Goehring, including password protection, strict management of “read-only” and “write-only” authors (e.g., Microsoft Office files Advanced Properties setting for Security & Protection).
  - b. System administrators will not be able to access files because they will not be saved on a shared network.
2. Access to devices with profile data will be logged.
3. Back-up
  - a. Back-up media will be secured from access by unauthorized persons.
4. System Changes & Management
  - a. Connections to services running on the host computer while the device with profile data are active will be limited to only the authorized users of the service.
  - b. Software firewalls, hardware firewalls, and service configuration will be in place.
5. Computer Virus Protection
  - a. Anti-virus and anti-spyware software will be installed and enabled for all computers/devices with profile data, and configured for daily scanning.
  - b. Integrity checking of devices with profile data will be conducted every 30 days.
6. There will only be two (2) copies of the storage device file containing the data – one copy will be on a secure device at Degge containing profile data for both US DoD and HIRD; HealthCore (Scott Quinlan) will maintain copies of the HIRD profile data.
  - a. Both storage devices will be encrypted and password protected to prevent unauthorized access.
7. All copies of the profile data will be destroyed according to a timeframe determined in collaboration with Sanofi. Data destruction will occur in the following ways:
  - a. For data provided on either CD-ROM or DVD will be shredded; and
  - b. Electronically shredded via “File Shredder” software. Software contains five options for shredding algorithms, ranging from simple one pass to DoD 5220-22.M to Guttman algorithm with 35 passes.



**SLD ADJUDICATION PANEL REVIEW FORM**  
***SERIOUS LIVER INJURY/DISEASE***



## ADJUDICATION REVIEW FORM: SERIOUS LIVER DISEASE (SLD)

Reviewer: \_\_\_\_\_

Review Batch #: SLD-Batch #

Pt ID#: SLD- Gender: M / F Age:      Index Date:      /      /      Event:      /      /     

### SERIOUS LIVER INJURY/DISEASE (SLD): ADJUDICATION REVIEW FORM

**Instructions:** Please review the Patient Profile and **determine, based upon the characteristics and timing of the outcome event relative to the blinded study drug exposures, whether the liver event identified in bold red text suggests a serious liver injury/disease outcome event** as defined in the Study Protocol (definition provided on other side) and based on good clinical judgment.

**Please indicate “Yes”, “No”, or “Indeterminate”, and explain your decision.**

☐

**Yes. State your reasoning.**

**Confident (circle one): Y / N**

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**Estimated onset date of liver injury:**      /      /     

Please provide a description explaining the date of onset noted. You may list the relevant line numbers from the patient profile that support your response.

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☐

**No, not a case. State your reasoning:**

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☐

**Indeterminate, state your reasoning:**

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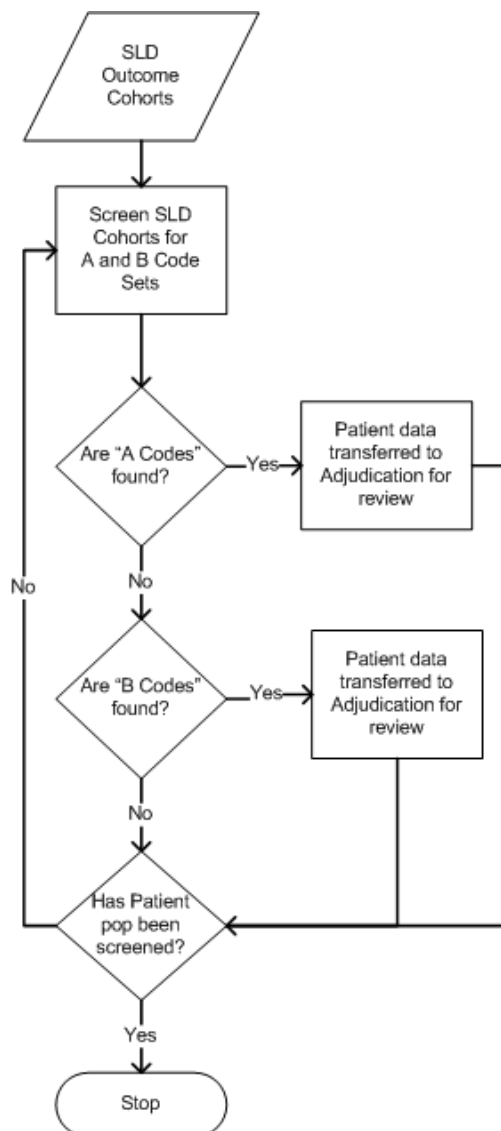
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**Reviewer Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

## ADJUDICATION REVIEW FORM: SERIOUS LIVER DISEASE (SLD)

Patients were selected for review based on hospitalized occurrences of selected liver injury/disease codes, defined in the study protocol, occurring after a patient's index date. The selection algorithm is provided below.



### **A CODES (Probably reflects serious liver injury/disease)**

#### **ICD-9-CM Diagnosis (Inpatient setting; any code position)**

570 Acute and subacute necrosis of liver  
 572.2 Hepatic coma  
 572.4 Hepatorenal syndrome  
 V42.7 Liver replaced by transplant

#### **ICD-9-CM Procedures (Inpatient setting; any code position)**

50.5 Liver transplant  
 50.51 Auxiliary liver transplant  
 50.59 Other transplant of liver

#### **CPT (Inpatient setting; any code position)**

47135 Liver allotransplantation; orthotopic, partial or whole  
 47136 Liver allotransplantation; heterotopic, partial or whole

### **B CODES (Possibly reflects serious liver injury/disease)**

#### **ICD-9-CM Diagnosis (must be a primary discharge diagnosis)**

277.4 Disorders of bilirubin excretion  
 571.5 Cirrhosis of liver without mention of alcohol  
 572.8 Other sequelae of chronic liver disease  
 573.0 Chronic passive congestion of liver  
 573.3 Hepatitis, unspecified  
 573.8 Other specified disorders of liver  
 573.9 Unspecified disorder of liver  
 782.4 Jaundice, unspecified  
 794.8 Nonspecific abnormal results of liver function test

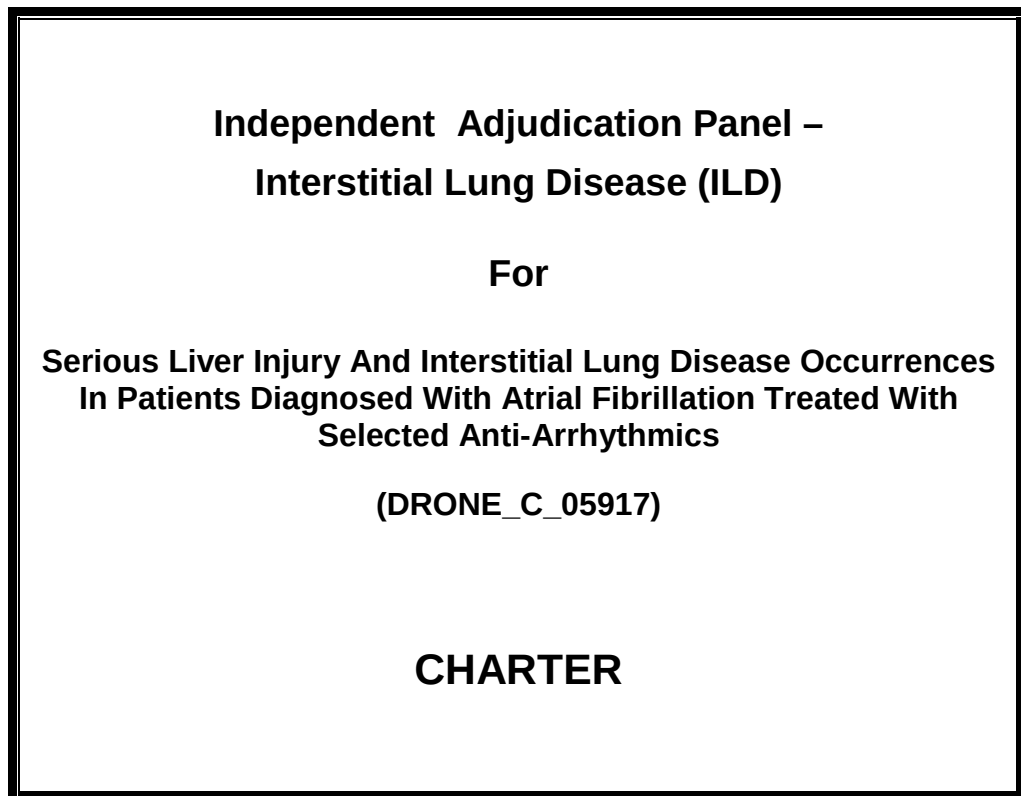
#### **ICD-9-CM Procedures (Inpatient setting; any code position)**

50.11 Closed (percutaneous) [needle] biopsy of liver  
 50.12 Open biopsy of liver  
 50.13 Transjugular liver biopsy  
 50.14 Laparoscopic liver biopsy  
 50.91 Percutaneous aspiration of liver

#### **CPT (Inpatient setting; any code position)**

47000 Biopsy of liver, needle; percutaneous  
 47001 Biopsy of liver, needle; done at time of other major procedure  
 47100 Biopsy of liver, wedge  
 78205 Liver imaging (SPECT)  
 78206 Liver imaging (SPECT); with vascular flow

**E. IAP: INTERSTITIAL LUNG DISEASE (ILD) - CHARTER**



March 12, 2015

# **Independent Adjudication Panel – Interstitial Lung Disease CHARTER**

**For**

**Serious Liver Injury/Disease And Interstitial Lung Disease Occurrences In  
Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-  
Arrhythmics**

**(DRONE\_C\_05917)**

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## Independent Adjudication Panel – Interstitial Lung Disease

For

### Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics (DRONE\_C\_05917)

#### CHARTER

## I. INTRODUCTION

Dronedarone (Multaq®) is an anti-arrhythmic drug with effects on all four classes of the Vaughan Williams' classification utilized for treatment of patients with non-permanent Atrial Fibrillation (AF). Dronedarone was initially authorized on 1 July 2009 in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

Post-marketing pharmacovigilance data of spontaneous reports indicate safety signals related to interstitial lung disease (ILD), and serious liver injury /disease (SLD). In order to examine these associations in the real-world setting, where dronedarone is approved for non-permanent AF/AFL, Sanofi requested a retrospective cohort study examining the association between dronedarone and comparator anti-arrhythmic drugs and these subsequent events among adults.

The Degge Group, Ltd., a drug safety consulting firm, has been retained to help in the original study design and coordination of an epidemiologic study titled, "*Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics (DRONE\_C\_05917)*". Degge is also charged with providing oversight management and content support of the Epidemiology Steering Committee and the Independent Adjudication Panels (IAP), and to contribute to the final analysis of the results.

## II. COMPOSITION OF THE ADJUDICATION PANEL

The IAP consists of three individuals who bring 3+ years of experience and expertise relating to interstitial lung disease in patients, have the expertise to review individual profiles from electronic medical records and/or administrative claims data, and general clinical management of patients with respiratory/lung disease.

The Panel includes:

- Judith K. Jones, MD, PhD, FISPE, *President & CEO*, The Degge Group, Ltd., Fairfax, VA, (**Panel Chair**)
- Kevin R. Flaherty, MD, MS, *Professor of Internal Medicine*, University of Michigan Health System, Ann Harbor
- David J. Lederer, MD, MS, *Associate Medical Director, NYP/Columbia Lung Transplant Program*, Columbia University Medical Center, New York
- Ganesh Raghu, MD, *Director, Center of Interstitial Lung Disease*, University of Washington Medical Center, Seattle

Dr. Judith K. Jones will Chair the Panel and the meetings and with assistance of Degge staff, maintain minutes of the meetings. The curriculum vitae of the Panelists will be attached.

### **III. MEMBERSHIP TERM**

Panel members are to serve for the term of the study, which is estimated to last for approximately two years. If a Panel member is unable to serve, the Panel Chairperson shall select a substitute. This substitute shall have the same duties and responsibilities as the other members.

### **IV. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST**

Members of the IAP represent that they have disclosed to the Panel Chair any and all conflicts of interest that would prevent their participation and performance on the Panel.

Members will be responsible for advising the Panel of any changes in their financial interests that may create a conflict of interest. Members who develop financial relationships that might be perceived to result in conflicts of interests or to impair objectivity will be asked to resign from the Panel or to divest themselves of those relationships/interests. If they resign, the Chair shall select a replacement to serve on the IAP.

### **V. DATA PROVIDED FOR REVIEW**

Degge will prepare and forward materials for the IAP to review. For the initial orientation meeting, the Panel members will receive the package insert for each of the study drugs, the Study Protocol, and additional background material relevant to this study. For subsequent meetings, the Chair and Degge staff will assure that Panel members have the appropriate materials at least one week prior to the planned meetings.

### **VI. DATA REVIEW AND EVALUATION**

Each member will review the information and data provided to the IAP independently. Individual patient profile information may be discussed at closed Panel meetings. Closed sessions will comprise only the Panel members and Degge administrative staff. The Panel meetings may consist of open sessions where employees of Sanofi and HealthCore may be involved to provide project overviews and status updates. Individual patient profile information will not be discussed in open sessions.

### **VII. MEETINGS**

An initial organizational meeting will be convened in person at Degge's office in Fairfax, Virginia. Representatives of Sanofi will provide participants with an overview of the Dronedarone history and current overall program. Degge will present the Study Protocol.

Panel members will be given the opportunity to familiarize themselves with all aspects of the observational study protocol and may ask any questions or concerns. A briefing binder of selected materials will be provided to Panel members to facilitate the discussions.

### **VIII. VOTING**

Since the Panel is small, all Panel members are required to be present in person or by telephone for a quorum, if a vote is to be cast. Decisions are based upon unanimous agreement. The Chairperson will not vote. There will be discussion only if a decision is not unanimous and decision is based upon a simple majority.



## **IX. DECISIONS OF THE INDEPENDENT ADJUDICATION PANEL**

The IAP is charged with determining whether interstitial lung disease outcome events are true cases as defined in the latest version of the Epidemiology Study Protocol. The specific procedures for adjudication are in **Attachment 1**.

## **X. MEETING MINUTES**

The Chair shall prepare minutes from the Panel meetings. To assist the Chair in this responsibility, a Degge staff member shall be designated by the Chair to take minutes during each meeting. The Chair shall edit these minutes and distribute to the other Panel members, Sanofi, and data partners within two weeks of the meeting. The minutes shall be approved by the Panel by email as well as during the following meeting to accurately reflect the Panel's opinions and conclusions regarding all reviewed issues.

## **XI. CONFIDENTIALITY**

All Panel members have agreed to and are bound by Confidentiality Agreements. All materials and information relating to this Panel shall be maintained strictly confidential pursuant to Degge's confidentiality agreement.

## **XII. SUNSHINE ACT REPORTING**

Federal law requires that pharmaceutical companies fully capture all transfers of value made to any covered US licensed health care provider (physicians, nurse practitioners, nurses, hospitals, clinics, PBMs, health insurance carriers, etc.). As such, Degge is responsible for reporting to Sanofi any and all financial payments made to Panel members, who are active licensed physicians, for their participation while serving on the Panel.

## ATTACHMENT 1. PATIENT PROFILE REVIEW & ADJUDICATION PROCEDURES

### Serious Liver Injury And Interstitial Lung Disease Occurrences In Patients Diagnosed With Atrial Fibrillation Treated With Selected Anti-Arrhythmics (DRONE\_C\_05917)

#### Independent Adjudication Panels

The Independent Adjudication Panels have been created to review and adjudicate potential cases identified in each of the study databases as described in the current *Study Protocol*.

#### I. Potential Case Identification

##### A. "Case" definition

A "Case" is defined as a patient who has an occurrence of outcome event code after the index date.

##### B. Review Cases identified via Selection Algorithm

A selection algorithm was developed to identify potential outcome events in patients that are in the cohort study conducted in the US DoD and HealthCore Integrated Research Database (HIRD™) databases. Patient Profiles of the potential cases will be provided to the IAP for outcome event adjudication and determination as defined in the study protocol.

##### C. Patient Profile Creation

Specifications on the layout of the Patient Profile will be provided to the analytic groups (Degge & HealthCore) involved in generating the profiles.

##### D. Receipt of Patient Profiles from Data Vendor

1. Patient profiles of potential cases will be provided to a Degge staff person in electronic format that is password protected.
2. The profile IDs and adjudicated status will be recorded in a tracking spreadsheet.

##### E. Storage of Patient Profiles

The creation and distribution of patient profile data from the US DoD and HIRD will adhere to Degge's Data Protection Policy, see **Attachment 2**. Copies are not provided to representatives of the sponsor, Sanofi, at any time.

##### F. IAP Review

The Panel, including the Chair, will be blinded to:

1. Study database, and
2. Study drugs of interest.

## II. Patient Profile Review

### A. Initial Review

1. Staff Screening/Verification – Degge staff will review all profiles to:
  - a. Record potential case information in outcome event tracking spreadsheet,
  - b. Assure study database name and study drugs of interest have been blinded,
  - c. Determine that a study outcome is present,
  - d. Attach corresponding event review form with event definitions.

### B. Adjudication / Reconciliation Review Process

1. All Panel members will familiarize themselves with the Protocol and the outcome event definitions to facilitate decisions.
2. Assignment of Cases. Depending on the number of potential cases to review, the IAP may meet face-to-face for 1 or 2 full days, or review password protected electronic files containing a large number of cases.
3. Each Panel member will initially review potential cases independently:
  - a. To determine based upon the characteristics and timing relative to the blinded study drug's exposure, whether the designated lung event suggests an interstitial lung disease outcome event as defined in the Study Protocol, and based on good clinical judgment. Event determination includes assignment as either:
    - “Yes” – the information provided meets the outcome event criteria,
    - “No” – the information provided does not meet the outcome event criteria, or
    - “Indeterminate” – the information provided does not meet the outcome event criteria, as defined in the study protocol, but the clinical picture suggests an outcome event.
4. Outcome Event Tabulation and Reconciliation:
  - a. Reviewer decisions will be tabulated for each case.
    - i. Cases with unanimous Reviewer agreement will have that determination assigned in the database. No further discussion will be needed.
    - ii. If disagreement between the Panel members exists, the patient profile will be discussed in a formal meeting where all three Panel members and the Chair are present. The Chair will lead the discussion. Panel members will each present reasoning for their decision, followed by a final vote. If a consensus is reached, that determination will be assigned in the database; else the event will be assigned as “Indeterminate”.

### C. Reporting Outcome Events back to Study Databases

Upon the IAP's completed review of all potential events, the final event determination will be provided back to the respective study databases to continue the study analyses.

More detailed procedures and forms to facilitate decision-making may be developed in the first reviews of actual cases.

## ATTACHMENT 2: DATA PROTECTION POLICY – PROJECT SPECIFIC

**Project:** Sanofi: Dronedarone Surveillance Study      **Project #:** 0204-110  
**Location:** The Degge Group, Ltd. office only  
**Required:** Restricted Access – Fixed Storage Media  
**PM:** Earl Goehring, Managing Director, Research

### I. Restricted Access – Fixed Storage Media

1. Physical access to profile data will be restricted to authorized persons by the following:
  - a. All non-removable or (re-)writable storage media with profile data will be configured with file systems that support access control. These include:
    - i. Password protection of all devices storing profile data.
    - ii. Data files will have robust security settings in place managed by Earl Goehring, including password protection, strict management of “read-only” and “write-only” authors (e.g., Microsoft Office files Advanced Properties setting for Security & Protection).
  - b. System administrators will not be able to access files because they will not be saved on a shared network.
2. Access to devices with profile data will be logged.
3. Back-up
  - a. Back-up media will be secured from access by unauthorized persons.
4. System Changes & Management
  - a. Connections to services running on the host computer while the device with profile data are active will be limited to only the authorized users of the service.
  - b. Software firewalls, hardware firewalls, and service configuration will be in place.
5. Computer Virus Protection
  - a. Anti-virus and anti-spyware software will be installed and enabled for all computers/devices with profile data, and configured for daily scanning.
  - b. Integrity checking of devices with profile data will be conducted every 30 days.
6. There will only be two (2) copies of the storage device file containing the data – one copy will be on a secure device at Degge containing profile data for both US DoD and HIRD; HealthCore (Scott Quinlan) will maintain copies of the HIRD profile data.
  - a. Both storage devices will be encrypted and password protected to prevent unauthorized access.
7. All copies of the profile data will be destroyed according to a timeframe determined in collaboration with Sanofi. Data destruction will occur in the following ways:
  - a. For data provided on either CD-ROM or DVD will be shredded; and
  - b. Electronically shredded via “File Shredder” software. Software contains five options for shredding algorithms, ranging from simple one pass to DoD 5220-22.M to Guttman algorithm with 35 passes.

**ILD ADJUDICATION PANEL REVIEW FORM**

***INTERSTITIAL LUNG DISEASE-NARROW DEFINITION***



## ADJUDICATION REVIEW FORM: INTERSTITIAL LUNG DISEASE-NARROW

Reviewer: \_\_\_\_\_

Review Batch #: ILD-N Batch #

Pt ID#: ILD- Gender: M / F Age:      Index Date:      /      /      Event:      /      /     

**Instructions:** Please review the Patient Profile and **determine, based upon the characteristics and timing of the outcome event relative to the blinded study drug exposures, whether the lung event identified in bold red text suggests an interstitial lung disease outcome event** as defined in the Study Protocol (definition provided on other side) and based on good clinical judgment.

**Please indicate “Yes”, “No”, or “Indeterminate”, and explain your decision.**

☐

**Yes. State your reasoning.**

**Confident (circle one): Y / N**

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**Estimated onset date of interstitial lung disease:**      /      /     

Please provide a description explaining the date of onset noted. You may list the relevant line numbers from the patient profile that support your response.

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**No, not a case. State your reasoning:**

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☐

**Indeterminate, state your reasoning:**

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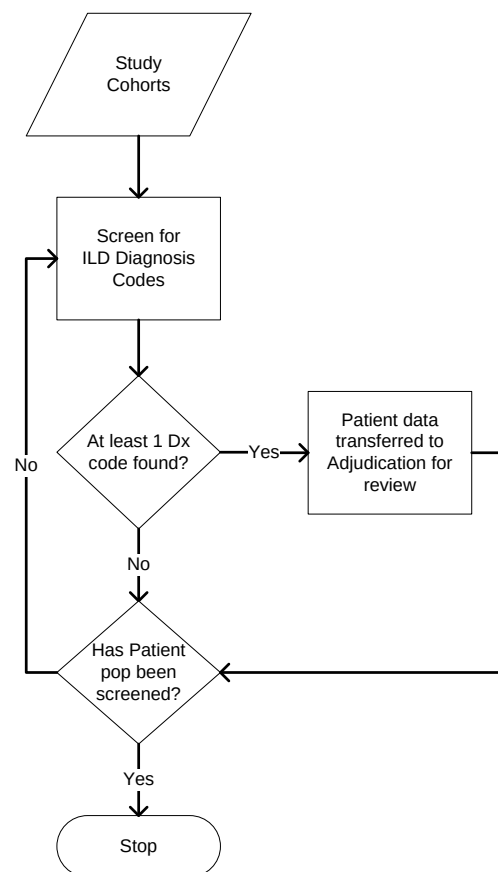
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**Reviewer Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

## ADJUDICATION REVIEW FORM: INTERSTITIAL LUNG DISEASE-NARROW

Patients were selected for review based on hospitalized occurrences of selected interstitial lung disease-narrow codes as defined in the study protocol, occurring after a patient's index date. The selection algorithm is provided below.



**Occurrence must be the primary discharge diagnosis code.**

| ICD-9-CM Code | Description                                                      |
|---------------|------------------------------------------------------------------|
| 515           | Post-inflammatory pulmonary fibrosis                             |
| 516.3         | Idiopathic fibrosing alveolitis                                  |
| 516.30        | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31        | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32        | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33        | Acute interstitial pneumonitis (AIP)                             |
| 516.34        | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35        | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36        | Cryptogenic organizing pneumonia (COP)                           |
| 516.37        | Desquamative interstitial pneumonia (DIP)                        |
| 516.8         | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9         | Unspecified alveolar and parietoalveolar pneumonopathy           |



## **F. SAMPLE PATIENT PROFILES**

### Serious Liver Injury/Disease Patient Profiles

Patient ID: SLD-0055

Patient ID: SLD-0126

### Interstitial Lung Disease Patient Profiles

Patient ID: ILD-0075

Patient ID: ILD-0088



## PATIENT PROFILE LAYOUT

**Header information - this information lists the Patient ID, gender, age at index date, Index Date, and date of suspected outcome event.**

| Patient ID #      | Age:                               | Gender:        | Index Date:              | Event Date:                                                        | Date of Death: |
|-------------------|------------------------------------|----------------|--------------------------|--------------------------------------------------------------------|----------------|
| De-identified ID# | Patient's age as of the Index Date | Male or Female | Date of Index Study Drug | First occurrence after the index date of a suspected outcome event | Date of Death  |

**Patient's Medical History - medical/pharmacy encounter data is laid out in chronological order by the services rendered, oldest records appearing at the beginning and recent records at the bottom.**

| Line # | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code | POS | Provider Specialty | Seq # | Code Description | Medication Name | Days Supply | QTY | Drug Formulation | Source | Record # |
|--------|-----------------|-----------------------------|----------------|-----------|------|-----|--------------------|-------|------------------|-----------------|-------------|-----|------------------|--------|----------|
|--------|-----------------|-----------------------------|----------------|-----------|------|-----|--------------------|-------|------------------|-----------------|-------------|-----|------------------|--------|----------|

### Column definitions:

|                              |                                                                                                                                                                                                                                                                    |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Line #                       | Sequential line number beginning with "1"                                                                                                                                                                                                                          |
| Time from Index              | Displays the number of days prior to the index date (e.g., -180, 180 days prior to the index date); and the number of days after the index date (e.g., 240)                                                                                                        |
| Date of Service / Admit Date | Contains the date of service for medical and pharmacy transactions. For inpatient stays, this date is the admission date.                                                                                                                                          |
| Discharge Date               | For code type=DX, PX, and CPT this date is the inpatient discharge date for inpatient stays.                                                                                                                                                                       |
| Code Type                    | Identifies the type of service transaction: <b>DX</b> = ICD-9-CM diagnosis code; <b>PX</b> = ICD-9-CM procedure code, CPT code, or HCPCS code; <b>RX</b> = Medication                                                                                              |
| Code                         | Actual code value reported for that transaction. For example, ICD-9-CM diagnosis/procedure codes, CPT codes, National Drug Codes (NDC)                                                                                                                             |
| POS                          | Place of Treatment (Services): Inpt (Hospital inpatient) indicates services that were performed at an inpatient hospital setting.                                                                                                                                  |
| Provider Specialty           | See Provider Specialty Codes Tabs for definitions                                                                                                                                                                                                                  |
| Seq #                        | The order in which the <b>diagnosis codes</b> appear on the claim/record form. 1=Primary, 2= secondary, etc...                                                                                                                                                     |
| Code Description             | Corresponding description of the code.                                                                                                                                                                                                                             |
| Medication Name              | Name of the medication dispensed                                                                                                                                                                                                                                   |
| Days Supply                  | For RX records, this value is the Days Supply.                                                                                                                                                                                                                     |
| QTY                          | For RX records, this value is the quantity dispensed.                                                                                                                                                                                                              |
| Drug Formulation             | For RX records, this is the drug formulation.                                                                                                                                                                                                                      |
| Source                       | This is the source of the transaction. <b>CAPER</b> =Direct Care-ProfessionalServices; <b>SIDR</b> =Direct Care-Inpt Records; <b>TEDN</b> =Purchased Care-Professional Services; <b>TEDI</b> =Purchased Care-Inpt Records; <b>PDTS</b> =Pharmacy Data Transactions |
| Record #                     | This number identifies the services/encounters associated with a transaction. There may be more than one transaction on a single day.                                                                                                                              |

### Color Coding

|                  |                                                                |
|------------------|----------------------------------------------------------------|
| Yellow highlight | Index study drugs are highlighted in yellow.                   |
| Orange highlight | Non-index study drugs are highlighted in orange.               |
| Olive highlight  | Skilled nursing facility stays are highlighted in olive green. |

Hospitalizations (admit to discharge) are highlighted in gray.

**Hospital Facility Records containing discharge diagnoses/procedures are in bold black text.**

**Hospitalized outcome events of interest are in bold red text.**

Non-hospitalized outcome events will be in plain red text.



Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 1           | -357            | 12/15/2008                  |                | Rx        | 00832121510 |     |                    |       |                                           | Jantoven               | 90          | 90  | Tablet                         | PDTS   | 1      |
| 2           | -355            | 12/17/2008                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 2      |
| 3           | -321            | 01/20/2009                  |                | Dx        | 34540       |     | Neuro              | 1     | Loc Epilepsy W Complex Seizure            |                        |             |     |                                | TEDN   | 3      |
| 4           | -321            | 01/20/2009                  |                | Px        | 99213       |     | Neuro              | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 3      |
| 5           | -315            | 01/26/2009                  |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 4      |
| 6           | -312            | 01/29/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 5      |
| 7           | -312            | 01/29/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 5      |
| 8           | -312            | 01/29/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 5      |
| 9           | -312            | 01/29/2009                  |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 5      |
| 10          | -298            | 02/12/2009                  |                | Dx        | 5853        |     | Grppract           | 1     | Chronic Kidney Disease Stage Iii          |                        |             |     |                                | TEDN   | 7      |
| 11          | -298            | 02/12/2009                  |                | Dx        | 2859        |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 7      |
| 12          | -298            | 02/12/2009                  |                | Dx        | 4011        |     | Grppract           | 3     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 7      |
| 13          | -298            | 02/12/2009                  |                | Px        | 99212       |     | Grppract           | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                | TEDN   | 7      |
| 14          | -298            | 02/12/2009                  |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide             | 30          | 60  | Tablet                         | PDTS   | 6      |
| 15          | -284            | 02/26/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 8      |
| 16          | -284            | 02/26/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 8      |
| 17          | -284            | 02/26/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 8      |
| 18          | -284            | 02/26/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 8      |
| 19          | -284            | 02/26/2009                  |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 9      |
| 20          | -284            | 02/26/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 10     |
| 21          | -278            | 03/04/2009                  |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                                | TEDN   | 11     |
| 22          | -278            | 03/04/2009                  |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                                | TEDN   | 11     |
| 23          | -278            | 03/04/2009                  |                | Px        | A4371       |     | Medic              | 1     | Skin Barrier Powder Per Oz                |                        |             |     |                                | TEDN   | 12     |
| 24          | -278            | 03/04/2009                  |                | Px        | A4394       |     | Medic              | 1     | Ostomy Pouch Liq Deodorant                |                        |             |     |                                | TEDN   | 13     |
| 25          | -278            | 03/04/2009                  |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                                | TEDN   | 14     |
| 26          | -278            | 03/04/2009                  |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                                | TEDN   | 15     |
| 27          | -278            | 03/04/2009                  |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                                | TEDN   | 16     |
| 28          | -278            | 03/04/2009                  |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                                | TEDN   | 17     |
| 29          | -276            | 03/06/2009                  |                | Rx        | 25010040515 |     |                    |       |                                           | Mephyton               | 1           | 2   | Tablet                         | PDTS   | 18     |
| 30          | -275            | 03/07/2009                  |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 30          | 60  | Tablet, Sustained Release 24hr | PDTS   | 19     |
| 31          | -273            | 03/09/2009                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 20     |
| 32          | -270            | 03/12/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 21     |
| 33          | -270            | 03/12/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 21     |
| 34          | -270            | 03/12/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 21     |
| 35          | -270            | 03/12/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 21     |
| 36          | -270            | 03/12/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 22     |
| 37          | -269            | 03/13/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                         | PDTS   | 23     |
| 38          | -265            | 03/17/2009                  |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 24     |
| 39          | -261            | 03/21/2009                  |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide             | 30          | 60  | Tablet                         | PDTS   | 25     |

Patient ID: SLD-0050

Age: 80 Gender: F Indexdate: 12/07/2009 Event Date: 01/26/2010 Date of Death: 02/03/2010

| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description      | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|--------------------------------|--------|--------|
| 40          | -242            | 04/09/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 26     |
| 41          | -242            | 04/09/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 26     |
| 42          | -242            | 04/09/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 26     |
| 43          | -242            | 04/09/2009                 |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 26     |
| 44          | -238            | 04/13/2009                 |                | Rx        | 49884040501 |     |                    |       |                                           | Metoprolol Succinate        | 30          | 90  | Tablet, Sustained Release 24hr | PDTS   | 27     |
| 45          | -237            | 04/14/2009                 |                | Rx        | 62175011843 |     |                    |       |                                           | Omeprazole                  | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 28     |
| 46          | -231            | 04/20/2009                 |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                                | TEDN   | 29     |
| 47          | -231            | 04/20/2009                 |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                             |             |     |                                | TEDN   | 29     |
| 48          | -231            | 04/20/2009                 |                | Dx        | 2720        |     | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                             |             |     |                                | TEDN   | 29     |
| 49          | -231            | 04/20/2009                 |                | Dx        | 5939        |     | Cardvasc           | 4     | Uns Disorder Kidney/Ureter                |                             |             |     |                                | TEDN   | 29     |
| 50          | -231            | 04/20/2009                 |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 29     |
| 51          | -230            | 04/21/2009                 |                | Rx        | 68462014645 |     |                    |       |                                           | Nitroglycerin               | 15          | 25  | Tablet, Sublingual             | PDTS   | 30     |
| 52          | -228            | 04/23/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 31     |
| 53          | -228            | 04/23/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 31     |
| 54          | -228            | 04/23/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 31     |
| 55          | -228            | 04/23/2009                 |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                             |             |     |                                | TEDN   | 31     |
| 56          | -228            | 04/23/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                             |             |     |                                | TEDN   | 32     |
| 57          | -227            | 04/24/2009                 |                | Dx        | 42731       |     | Grppract           | 1     | Atrial Fibrillation                       |                             |             |     |                                | TEDN   | 33     |
| 58          | -227            | 04/24/2009                 |                | Dx        | 41400       |     | Grppract           | 2     | Coronary Athrscler Uns Vessel             |                             |             |     |                                | TEDN   | 33     |
| 59          | -227            | 04/24/2009                 |                | Dx        | 2449        |     | Grppract           | 3     | Uns Hypothyroidism                        |                             |             |     |                                | TEDN   | 33     |
| 60          | -227            | 04/24/2009                 |                | Dx        | 53081       |     | Grppract           | 4     | Esophageal Reflux                         |                             |             |     |                                | TEDN   | 33     |
| 61          | -227            | 04/24/2009                 |                | Px        | 99499       |     | Grppract           | 1     | Unlisted Evaluation And Management Servic |                             |             |     |                                | TEDN   | 33     |
| 62          | -220            | 05/01/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                     | 30          | 36  | Capsule (Hard, Soft, Etc.)     | PDTS   | 34     |
| 63          | -218            | 05/03/2009                 |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL                   | 90          | 180 | Tablet, Sustained Release 24hr | PDTS   | 35     |
| 64          | -214            | 05/07/2009                 |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                         | PDTS   | 36     |
| 65          | -203            | 05/18/2009                 |                | Rx        | 00093089005 |     |                    |       |                                           | Propoxyphene Napsylate-Apap | 15          | 60  | Tablet                         | PDTS   | 37     |
| 66          | -200            | 05/21/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                     | 56          | 72  | Capsule (Hard, Soft, Etc.)     | PDTS   | 38     |
| 67          | -189            | 06/01/2009                 |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                         | PDTS   | 39     |
| 68          | -189            | 06/01/2009                 |                | Rx        | 00378020893 |     |                    |       |                                           | Furosemide                  | 30          | 60  | Tablet                         | PDTS   | 40     |
| 69          | -186            | 06/04/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 41     |
| 70          | -186            | 06/04/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 41     |
| 71          | -186            | 06/04/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                             |             |     |                                | TEDN   | 41     |
| 72          | -186            | 06/04/2009                 |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                | TEDN   | 41     |
| 73          | -186            | 06/04/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                             |             |     |                                | TEDN   | 42     |
| 74          | -184            | 06/06/2009                 |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                         | PDTS   | 43     |
| 75          | -184            | 06/06/2009                 |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin                 | 90          | 90  | Tablet                         | PDTS   | 44     |
| 76          | -174            | 06/16/2009                 |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin                  | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 45     |
| 77          | -172            | 06/18/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                             |             |     |                                | TEDN   | 46     |
| 78          | -172            | 06/18/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                             |             |     |                                | TEDN   | 46     |

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| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation               | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 79          | -172            | 06/18/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 46     |
| 80          | -172            | 06/18/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 46     |
| 81          | -172            | 06/18/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 47     |
| 82          | -154            | 07/06/2009                  |                | Rx        | 51672403001 |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                         | PDTS   | 48     |
| 83          | -153            | 07/07/2009                  |                | Dx        | 34540       |     | Neuro              | 1     | Loc Epilepsy W Complex Seizure            |                        |             |     |                                | TEDN   | 49     |
| 84          | -153            | 07/07/2009                  |                | Px        | 99214       |     | Neuro              | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 49     |
| 85          | -147            | 07/13/2009                  |                | Dx        | V431        |     | Ophth              | 1     | Lens Replaced By Oth Means                |                        |             |     |                                | TEDN   | 51     |
| 86          | -147            | 07/13/2009                  |                | Px        | 92014       |     | Ophth              | 1     | Ophth Medical Xm&eval Comprhnsv Estab Pt  |                        |             |     |                                | TEDN   | 51     |
| 87          | -147            | 07/13/2009                  |                | Px        | 92015       |     | Ophth              | 1     | Determination Refractive State            |                        |             |     |                                | TEDN   | 52     |
| 88          | -147            | 07/13/2009                  |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 50     |
| 89          | -146            | 07/14/2009                  |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                                | TEDN   | 53     |
| 90          | -146            | 07/14/2009                  |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                                | TEDN   | 53     |
| 91          | -146            | 07/14/2009                  |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                                | TEDN   | 54     |
| 92          | -146            | 07/14/2009                  |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                                | TEDN   | 55     |
| 93          | -146            | 07/14/2009                  |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                                | TEDN   | 56     |
| 94          | -146            | 07/14/2009                  |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                                | TEDN   | 57     |
| 95          | -144            | 07/16/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 58     |
| 96          | -144            | 07/16/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 58     |
| 97          | -144            | 07/16/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 58     |
| 98          | -144            | 07/16/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 58     |
| 99          | -144            | 07/16/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 59     |
| 100         | -140            | 07/20/2009                  |                | Rx        | 60429015701 |     |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 60     |
| 101         | -130            | 07/30/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 61     |
| 102         | -130            | 07/30/2009                  |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 61     |
| 103         | -130            | 07/30/2009                  |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 61     |
| 104         | -130            | 07/30/2009                  |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 61     |
| 105         | -130            | 07/30/2009                  |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 62     |
| 106         | -130            | 07/30/2009                  |                | Dx        | 5853        |     | Grpprac            | 1     | Chronic Kidney Disease Stage Iii          |                        |             |     |                                | TEDN   | 63     |
| 107         | -130            | 07/30/2009                  |                | Dx        | 2859        |     | Grpprac            | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 63     |
| 108         | -130            | 07/30/2009                  |                | Dx        | 58881       |     | Grpprac            | 3     | Sec Hyperparathyroidism Renal             |                        |             |     |                                | TEDN   | 63     |
| 109         | -130            | 07/30/2009                  |                | Dx        | 4011        |     | Grpprac            | 4     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 63     |
| 110         | -130            | 07/30/2009                  |                | Px        | 99213       |     | Grpprac            | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                                | TEDN   | 63     |
| 111         | -126            | 08/03/2009                  |                | Rx        | 64125011610 |     |                    |       |                                           | Furosemide             | 90          | 90  | Tablet                         | PDTS   | 64     |
| 112         | -114            | 08/15/2009                  |                | Rx        | 00228266650 |     |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 65     |
| 113         | -102            | 08/27/2009                  |                | Rx        | 68382005401 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                         | PDTS   | 66     |
| 114         | -98             | 08/31/2009                  |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 67     |
| 115         | -97             | 09/01/2009                  |                | Rx        | 00781518201 |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 68     |
| 116         | -91             | 09/07/2009                  |                | Rx        | 24658021310 |     |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 69     |
| 117         | -88             | 09/10/2009                  |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 70     |

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|-------------|-----------------|----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 118         | -88             | 09/10/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 70     |
| 119         | -88             | 09/10/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 70     |
| 120         | -88             | 09/10/2009                 |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 70     |
| 121         | -74             | 09/24/2009                 |                | Dx        | 2859        |     | Patho              | 1     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 71     |
| 122         | -74             | 09/24/2009                 |                | Px        | 83912       |     | Patho              | 1     | Molecular Diagnostics Interpretation & Re |                        |             |     |                                | TEDN   | 71     |
| 123         | -71             | 09/27/2009                 |                | Rx        | 00186109005 |     |                    |       |                                           | Toprol XL              | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 72     |
| 124         | -69             | 09/29/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 73     |
| 125         | -60             | 10/08/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 74     |
| 126         | -60             | 10/08/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 74     |
| 127         | -60             | 10/08/2009                 |                | Dx        | 2859        |     | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 74     |
| 128         | -60             | 10/08/2009                 |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 74     |
| 129         | -60             | 10/08/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 75     |
| 130         | -48             | 10/20/2009                 |                | Dx        | 4293        |     | Grppract           | 1     | Cardiomegaly                              |                        |             |     |                                | TEDN   | 76     |
| 131         | -48             | 10/20/2009                 |                | Px        | 71020       |     | Grppract           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                | TEDN   | 76     |
| 132         | -48             | 10/20/2009                 |                | Px        | 93010       |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                                | TEDN   | 77     |
| 133         | -48             | 10/20/2009                 |                | Dx        | 78650       |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                                | TEDN   | 78     |
| 134         | -48             | 10/20/2009                 |                | Dx        | 78605       |     | Facility           | 2     | Shortness Breath                          |                        |             |     |                                | TEDN   | 78     |
| 135         | -48             | 10/20/2009                 |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 78     |
| 136         | -48             | 10/20/2009                 |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                                | TEDN   | 78     |
| 137         | -48             | 10/20/2009                 |                | Dx        | 34590       |     | Facility           | 5     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                                | TEDN   | 78     |
| 138         | -48             | 10/20/2009                 |                | Dx        | 73300       |     | Facility           | 6     | Osteoporosis Unspec                       |                        |             |     |                                | TEDN   | 78     |
| 139         | -48             | 10/20/2009                 |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                                | TEDN   | 78     |
| 140         | -48             | 10/20/2009                 |                | Dx        | 53081       |     | Facility           | 8     | Esophageal Reflux                         |                        |             |     |                                | TEDN   | 78     |
| 141         | -48             | 10/20/2009                 |                | Px        | 36415       |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                                | TEDN   | 78     |
| 142         | -48             | 10/20/2009                 |                | Px        | 80053       |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                                | TEDN   | 79     |
| 143         | -48             | 10/20/2009                 |                | Px        | 82553       |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                                | TEDN   | 80     |
| 144         | -48             | 10/20/2009                 |                | Px        | 83735       |     | Facility           | 1     | Magnesium                                 |                        |             |     |                                | TEDN   | 81     |
| 145         | -48             | 10/20/2009                 |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                                | TEDN   | 82     |
| 146         | -48             | 10/20/2009                 |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                                | TEDN   | 83     |
| 147         | -48             | 10/20/2009                 |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                                | TEDN   | 84     |
| 148         | -48             | 10/20/2009                 |                | Px        | 85730       |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                                | TEDN   | 85     |
| 149         | -48             | 10/20/2009                 |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                                | TEDN   | 86     |
| 150         | -48             | 10/20/2009                 |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                                | TEDN   | 87     |
| 151         | -48             | 10/20/2009                 |                | Px        | 99284       |     | Facility           | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                                | TEDN   | 88     |
| 152         | -48             | 10/20/2009                 |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                                | TEDN   | 89     |
| 153         | -47             | 10/21/2009                 |                | Dx        | 78650       |     | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                                | TEDN   | 90     |
| 154         | -47             | 10/21/2009                 |                | Dx        | 42731       |     | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 90     |
| 155         | -47             | 10/21/2009                 |                | Dx        | 4019        |     | Fp                 | 3     | Unspecified Essential Hypertension        |                        |             |     |                                | TEDN   | 90     |
| 156         | -47             | 10/21/2009                 |                | Dx        | 78039       |     | Fp                 | 4     | Other Convulsions                         |                        |             |     |                                | TEDN   | 90     |



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|-------------|-----------------|----------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 157         | -47             | 10/21/2009                 |                | Px        | 99234       |     | Fp                 | 1     | Observation/Inpatient Hospital Care Low S |                        |             |     |                            | TEDN   | 90     |
| 158         | -47             | 10/21/2009                 |                | Dx        | V442        |     | Medic              | 1     | Ileostomy Status                          |                        |             |     |                            | TEDN   | 91     |
| 159         | -47             | 10/21/2009                 |                | Px        | A4365       |     | Medic              | 1     | Adhes Remover Wipes Any Type              |                        |             |     |                            | TEDN   | 91     |
| 160         | -47             | 10/21/2009                 |                | Px        | A4406       |     | Medic              | 1     | Pectin Based Ostomy Paste                 |                        |             |     |                            | TEDN   | 92     |
| 161         | -47             | 10/21/2009                 |                | Px        | A4407       |     | Medic              | 1     | Ext Wear Ost Skn Barr <=4sq"              |                        |             |     |                            | TEDN   | 93     |
| 162         | -47             | 10/21/2009                 |                | Px        | A5063       |     | Medic              | 1     | Drain Ostomy Pouch W/Flange               |                        |             |     |                            | TEDN   | 94     |
| 163         | -47             | 10/21/2009                 |                | Px        | A5120       |     | Medic              | 1     | Skin Barrier, Wipe Or Swab                |                        |             |     |                            | TEDN   | 95     |
| 164         | -47             | 10/21/2009                 |                | Dx        | 78650       |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                            | TEDN   | 96     |
| 165         | -47             | 10/21/2009                 |                | Dx        | 78605       |     | Facility           | 2     | Shortness Breath                          |                        |             |     |                            | TEDN   | 96     |
| 166         | -47             | 10/21/2009                 |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 96     |
| 167         | -47             | 10/21/2009                 |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                            | TEDN   | 96     |
| 168         | -47             | 10/21/2009                 |                | Dx        | 34590       |     | Facility           | 5     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                            | TEDN   | 96     |
| 169         | -47             | 10/21/2009                 |                | Dx        | 73300       |     | Facility           | 6     | Osteoporosis Unspec                       |                        |             |     |                            | TEDN   | 96     |
| 170         | -47             | 10/21/2009                 |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                            | TEDN   | 96     |
| 171         | -47             | 10/21/2009                 |                | Dx        | 53081       |     | Facility           | 8     | Esophageal Reflux                         |                        |             |     |                            | TEDN   | 96     |
| 172         | -47             | 10/21/2009                 |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                            | TEDN   | 96     |
| 173         | -47             | 10/21/2009                 |                | Px        | 82553       |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                            | TEDN   | 97     |
| 174         | -47             | 10/21/2009                 |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                            | TEDN   | 98     |
| 175         | -47             | 10/21/2009                 |                | Px        | 94760       |     | Facility           | 1     | Noninvasive Ear/Pulse Oximetry Single Det |                        |             |     |                            | TEDN   | 99     |
| 176         | -47             | 10/21/2009                 |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                            | TEDN   | 100    |
| 177         | -47             | 10/21/2009                 |                | Px        | 99234       |     | Facility           | 1     | Observation/Inpatient Hospital Care Low S |                        |             |     |                            | TEDN   | 101    |
| 178         | -46             | 10/22/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                            | TEDN   | 102    |
| 179         | -46             | 10/22/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                            | TEDN   | 102    |
| 180         | -46             | 10/22/2009                 |                | Px        | 96372       |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                            | TEDN   | 102    |
| 181         | -46             | 10/22/2009                 |                | Px        | J0885       |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                            | TEDN   | 103    |
| 182         | -39             | 10/29/2009                 |                | Dx        | 78650       |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                            | TEDN   | 104    |
| 183         | -39             | 10/29/2009                 |                | Dx        | 53081       |     | Grppract           | 2     | Esophageal Reflux                         |                        |             |     |                            | TEDN   | 104    |
| 184         | -39             | 10/29/2009                 |                | Px        | 99499       |     | Grppract           | 1     | Unlisted Evaluation And Management Servic |                        |             |     |                            | TEDN   | 104    |
| 185         | -37             | 10/31/2009                 |                | Rx        | 62175011843 |     |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)      | PDTS   | 105    |
| 186         | -36             | 11/01/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.) | PDTS   | 106    |
| 187         | -33             | 11/04/2009                 |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 107    |
| 188         | -33             | 11/04/2009                 |                | Dx        | V171        |     | Cardvasc           | 2     | Family History Stroke                     |                        |             |     |                            | TEDN   | 107    |
| 189         | -33             | 11/04/2009                 |                | Dx        | V5869       |     | Cardvasc           | 3     | Encounter Long Term Use Oth Drugs         |                        |             |     |                            | TEDN   | 107    |
| 190         | -33             | 11/04/2009                 |                | Px        | 99242       |     | Cardvasc           | 1     | Office Consultation New/Estab Patient 30  |                        |             |     |                            | TEDN   | 107    |
| 191         | -18             | 11/19/2009                 |                | Dx        | 2841        |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                            | TEDN   | 108    |
| 192         | -18             | 11/19/2009                 |                | Dx        | 5569        |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                            | TEDN   | 108    |
| 193         | -18             | 11/19/2009                 |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 108    |
| 194         | -7              | 11/30/2009                 |                | Rx        | 68382005401 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                     | PDTS   | 109    |
| 195         | -6              | 12/01/2009                 |                | Rx        | 00074431730 |     |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.) | PDTS   | 110    |

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| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code  | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 196         | -4              | 12/03/2009                 |                | Dx        | 2841  |     | Intmed             | 1     | Pancytopenia                              |                        |             |     |                  | TEDN   | 111    |
| 197         | -4              | 12/03/2009                 |                | Dx        | 5569  |     | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                  | TEDN   | 111    |
| 198         | -4              | 12/03/2009                 |                | Px        | 96372 |     | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                  | TEDN   | 111    |
| 199         | -4              | 12/03/2009                 |                | Px        | J0885 |     | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                  | TEDN   | 112    |
| 200         | -1              | 12/06/2009                 |                | Dx        | 78650 |     | Radio              | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 116    |
| 201         | -1              | 12/06/2009                 |                | Px        | 71010 |     | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 116    |
| 202         | -1              | 12/06/2009                 |                | Dx        | 78650 |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 117    |
| 203         | -1              | 12/06/2009                 |                | Dx        | 5859  |     | Grppract           | 2     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 117    |
| 204         | -1              | 12/06/2009                 |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 117    |
| 205         | -1              | 12/06/2009                 |                | Dx        | 4019  |     | Grppract           | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 117    |
| 206         | -1              | 12/06/2009                 |                | Dx        | 2449  |     | Grppract           | 5     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 117    |
| 207         | -1              | 12/06/2009                 |                | Dx        | 34590 |     | Grppract           | 6     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                  | TEDN   | 117    |
| 208         | -1              | 12/06/2009                 |                | Dx        | V5861 |     | Grppract           | 7     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 117    |
| 209         | -1              | 12/06/2009                 |                | Dx        | V5869 |     | Grppract           | 8     | Encounter Long Term Use Oth Drugs         |                        |             |     |                  | TEDN   | 117    |
| 210         | -1              | 12/06/2009                 |                | Px        | 93010 |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 117    |
| 211         | -1              | 12/06/2009                 |                | Dx        | 78650 |     | Facility           | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 118    |
| 212         | -1              | 12/06/2009                 |                | Dx        | 5859  |     | Facility           | 2     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 118    |
| 213         | -1              | 12/06/2009                 |                | Dx        | 42731 |     | Facility           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 118    |
| 214         | -1              | 12/06/2009                 |                | Dx        | 4019  |     | Facility           | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 118    |
| 215         | -1              | 12/06/2009                 |                | Dx        | 2449  |     | Facility           | 5     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 118    |
| 216         | -1              | 12/06/2009                 |                | Dx        | 34590 |     | Facility           | 6     | Uns Epilepsy Wo Intract Epilepsy          |                        |             |     |                  | TEDN   | 118    |
| 217         | -1              | 12/06/2009                 |                | Dx        | V5861 |     | Facility           | 7     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 118    |
| 218         | -1              | 12/06/2009                 |                | Dx        | V5869 |     | Facility           | 8     | Encounter Long Term Use Oth Drugs         |                        |             |     |                  | TEDN   | 118    |
| 219         | -1              | 12/06/2009                 |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 118    |
| 220         | -1              | 12/06/2009                 |                | Px        | 71010 |     | Facility           | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 119    |
| 221         | -1              | 12/06/2009                 |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 120    |
| 222         | -1              | 12/06/2009                 |                | Px        | 82553 |     | Facility           | 1     | Creatine Kinase Mb Fraction Only          |                        |             |     |                  | TEDN   | 121    |
| 223         | -1              | 12/06/2009                 |                | Px        | 83735 |     | Facility           | 1     | Magnesium                                 |                        |             |     |                  | TEDN   | 122    |
| 224         | -1              | 12/06/2009                 |                | Px        | 84484 |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                  | TEDN   | 123    |
| 225         | -1              | 12/06/2009                 |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 124    |
| 226         | -1              | 12/06/2009                 |                | Px        | 85378 |     | Facility           | 1     | Fibrin Dgradj Products D-Dimer Qual/Semi  |                        |             |     |                  | TEDN   | 125    |
| 227         | -1              | 12/06/2009                 |                | Px        | 85610 |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 126    |
| 228         | -1              | 12/06/2009                 |                | Px        | 93005 |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                  | TEDN   | 127    |
| 229         | -1              | 12/06/2009                 |                | Px        | 99070 |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                  | TEDN   | 128    |
| 230         | -1              | 12/06/2009                 |                | Px        | 99284 |     | Facility           | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                  | TEDN   | 129    |
| 231         | -1              | 12/06/2009                 |                | Px        | 99291 |     | Facility           | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 130    |
| 232         | -1              | 12/06/2009                 |                | Px        | 99292 |     | Facility           | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 131    |
| 233         | -1              | 12/06/2009                 |                | Px        | 99499 |     | Facility           | 1     | Unlisted Evaluation And Management Serv   |                        |             |     |                  | TEDN   | 132    |
| 234         | -1              | 12/06/2009                 |                | Px        | A0425 |     | Facility           | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 133    |

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|-------------|-----------------|----------------------------|----------------|-----------|------------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 235         | -1              | 12/06/2009                 |                | Px        | A0426            |      | Facility           | 1     | Als 1                                     |                        |             |     |                                | TEDN   | 134    |
| 236         | -1              | 12/06/2009                 |                | Dx        | 42731            | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 113    |
| 237         | -1              | 12/06/2009                 |                | Px        | 93010            | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                                | TEDN   | 113    |
| 238         | -1              | 12/06/2009                 |                | Px        | 93306            | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                                | TEDN   | 114    |
| 239         | -1              | 12/06/2009                 |                | Px        | 99221            | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 30 Minutes      |                        |             |     |                                | TEDN   | 115    |
| 241         | 0               | 12/07/2009                 |                | Dx        | 4240             | Inpt | Cardvasc           | 1     | Mitral Valve Disorders                    |                        |             |     |                                | TEDN   | 136    |
| 242         | 0               | 12/07/2009                 |                | Dx        | 78659            | Inpt | Cardvasc           | 2     | Other Chest Pain                          |                        |             |     |                                | TEDN   | 136    |
| 243         | 0               | 12/07/2009                 |                | Px        | 99238            | Inpt | Cardvasc           | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                                | TEDN   | 136    |
| 240         | 0               | 12/07/2009                 | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | INITIAL FILL                   | PDTS   | 135    |
| 244         | 7               | 12/14/2009                 |                | Dx        | 42731            |      | Grpract            | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 137    |
| 245         | 7               | 12/14/2009                 |                | Dx        | 2720             |      | Grpract            | 2     | Pure Hypercholesterolemia                 |                        |             |     |                                | TEDN   | 137    |
| 246         | 7               | 12/14/2009                 |                | Dx        | 2449             |      | Grpract            | 3     | Uns Hypothyroidism                        |                        |             |     |                                | TEDN   | 137    |
| 247         | 7               | 12/14/2009                 |                | Px        | 99499            |      | Grpract            | 1     | Unlisted Evaluation And Management Servic |                        |             |     |                                | TEDN   | 137    |
| 248         | 10              | 12/17/2009                 |                | Dx        | 2841             |      | Intmed             | 1     | Pancytopenia                              |                        |             |     |                                | TEDN   | 138    |
| 249         | 10              | 12/17/2009                 |                | Dx        | 5569             |      | Intmed             | 2     | Uns Ulcerative Colitis                    |                        |             |     |                                | TEDN   | 138    |
| 250         | 10              | 12/17/2009                 |                | Dx        | 2859             |      | Intmed             | 3     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 138    |
| 251         | 10              | 12/17/2009                 |                | Px        | 96372            |      | Intmed             | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                                | TEDN   | 138    |
| 252         | 10              | 12/17/2009                 |                | Px        | J0885            |      | Intmed             | 1     | Epoetin Alfa, Non-Esrd                    |                        |             |     |                                | TEDN   | 139    |
| 253         | 12              | 12/19/2009                 |                | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | REFILL                         | PDTS   | 140    |
| 254         | 12              | 12/19/2009                 |                | Rx        | 24658021310      |      |                    |       |                                           | Simvastatin            | 90          | 90  | Tablet                         | PDTS   | 141    |
| 255         | 12              | 12/19/2009                 |                | Rx        | 00781518201      |      |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                         | PDTS   | 142    |
| 256         | 21              | 12/28/2009                 |                | Dx        | 42731            |      | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                                | TEDN   | 143    |
| 257         | 21              | 12/28/2009                 |                | Dx        | V5869            |      | Cardvasc           | 2     | Encounter Long Term Use Oth Drugs         |                        |             |     |                                | TEDN   | 143    |
| 258         | 21              | 12/28/2009                 |                | Px        | 99212            |      | Cardvasc           | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                | TEDN   | 143    |
| 259         | 33              | 01/09/2010                 |                | Rx        | 49884040510      |      |                    |       |                                           | Metoprolol Succinate   | 90          | 270 | Tablet, Sustained Release 24hr | PDTS   | 144    |
| 260         | 34              | 01/10/2010                 |                | Rx        | 00074431730      |      |                    |       |                                           | Zemplar                | 30          | 39  | Capsule (Hard, Soft, Etc.)     | PDTS   | 145    |
| 261         | 35              | 01/11/2010                 |                | Rx        | 49884040501      |      |                    |       |                                           | Metoprolol Succinate   | 30          | 90  | Tablet, Sustained Release 24hr | PDTS   | 146    |
| 262         | 42              | 01/18/2010                 |                | Rx        | 62175011843      |      |                    |       |                                           | Omeprazole             | 90          | 90  | Capsule, DR (Enteric)          | PDTS   | 147    |
| 263         | 42              | 01/18/2010                 |                | Rx        | 00228266650      |      |                    |       |                                           | Gabapentin             | 90          | 270 | Capsule (Hard, Soft, Etc.)     | PDTS   | 148    |
| 264         | 45              | 01/21/2010                 |                | Dx        | 5853             |      | Gp                 | 1     | Chronic Kidney Disease Stage iii          |                        |             |     |                                | TEDN   | 149    |
| 265         | 45              | 01/21/2010                 |                | Dx        | 2859             |      | Gp                 | 2     | Anemia Unspecified                        |                        |             |     |                                | TEDN   | 149    |
| 266         | 45              | 01/21/2010                 |                | Dx        | 58881            |      | Gp                 | 3     | Sec Hyperparathyroidism Renal             |                        |             |     |                                | TEDN   | 149    |
| 267         | 45              | 01/21/2010                 |                | Dx        | 4011             |      | Gp                 | 4     | Benign Essential Hypertension             |                        |             |     |                                | TEDN   | 149    |
| 268         | 45              | 01/21/2010                 |                | Px        | 99214            |      | Gp                 | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                | TEDN   | 149    |
| 269         | 45              | 01/21/2010                 |                | Px        | 99284            |      | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                                | TEDN   | 150    |
| 270         | 45              | 01/21/2010                 |                | Dx        | 7944             |      | Facility           | 1     | Abnormal Kidney Funct Study               |                        |             |     |                                | TEDN   | 151    |
| 271         | 45              | 01/21/2010                 |                | Dx        | 5939             |      | Facility           | 2     | Uns Disorder Kidney/Ureter                |                        |             |     |                                | TEDN   | 151    |
| 272         | 45              | 01/21/2010                 |                | Dx        | 2449             |      | Facility           | 3     | Uns Hypothyroidism                        |                        |             |     |                                | TEDN   | 151    |

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| Line Number | Time from Index | Date of Service/ Admit Date | Discharge Date | Code Type | Code  | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|-----------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 273         | 45              | 01/21/2010                  |                | Dx        | V8801 |     | Facility           | 4     | Acq Absence Both Cervix Uterus            |                        |             |     |                  | TEDN   | 151    |
| 274         | 45              | 01/21/2010                  |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 151    |
| 275         | 45              | 01/21/2010                  |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 152    |
| 276         | 45              | 01/21/2010                  |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 153    |
| 277         | 45              | 01/21/2010                  |                | Px        | 99283 |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                  | TEDN   | 154    |
| 278         | 50              | 01/26/2010                  |                | Dx        | 78900 |     | Radio              | 1     | Abdominal Pain Uns Site                   |                        |             |     |                  | TEDN   | 155    |
| 279         | 50              | 01/26/2010                  |                | Dx        | V6709 |     | Radio              | 2     | Follow-Up Follow Oth Surgery              |                        |             |     |                  | TEDN   | 155    |
| 280         | 50              | 01/26/2010                  |                | Px        | 71010 |     | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 155    |
| 281         | 50              | 01/26/2010                  |                | Px        | 72192 |     | Radio              | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 156    |
| 282         | 50              | 01/26/2010                  |                | Px        | 74150 |     | Radio              | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 157    |
| 283         | 50              | 01/26/2010                  |                | Dx        | 78900 |     | Facility           | 1     | Abdominal Pain Uns Site                   |                        |             |     |                  | TEDN   | 159    |
| 284         | 50              | 01/26/2010                  |                | Dx        | 4019  |     | Facility           | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 159    |
| 285         | 50              | 01/26/2010                  |                | Dx        | 53081 |     | Facility           | 3     | Esophageal Reflux                         |                        |             |     |                  | TEDN   | 159    |
| 286         | 50              | 01/26/2010                  |                | Dx        | 2724  |     | Facility           | 4     | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDN   | 159    |
| 287         | 50              | 01/26/2010                  |                | Dx        | 42731 |     | Facility           | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 159    |
| 288         | 50              | 01/26/2010                  |                | Dx        | 2859  |     | Facility           | 6     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 159    |
| 289         | 50              | 01/26/2010                  |                | Dx        | 5859  |     | Facility           | 7     | Chronic Kidney Disease Unspec             |                        |             |     |                  | TEDN   | 159    |
| 290         | 50              | 01/26/2010                  |                | Dx        | V442  |     | Facility           | 8     | Ileostomy Status                          |                        |             |     |                  | TEDN   | 159    |
| 291         | 50              | 01/26/2010                  |                | Px        | 36415 |     | Facility           | 1     | Collection Venous Blood Venipuncture      |                        |             |     |                  | TEDN   | 159    |
| 292         | 50              | 01/26/2010                  |                | Px        | 71010 |     | Facility           | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 160    |
| 293         | 50              | 01/26/2010                  |                | Px        | 72192 |     | Facility           | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 161    |
| 294         | 50              | 01/26/2010                  |                | Px        | 74150 |     | Facility           | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 162    |
| 295         | 50              | 01/26/2010                  |                | Px        | 80053 |     | Facility           | 1     | Comprehensive Metabolic Panel             |                        |             |     |                  | TEDN   | 163    |
| 296         | 50              | 01/26/2010                  |                | Px        | 81001 |     | Facility           | 1     | Urnl Dip Stick/Tablet Reagent Auto Micro  |                        |             |     |                  | TEDN   | 164    |
| 297         | 50              | 01/26/2010                  |                | Px        | 82150 |     | Facility           | 1     | Amylase                                   |                        |             |     |                  | TEDN   | 165    |
| 298         | 50              | 01/26/2010                  |                | Px        | 83690 |     | Facility           | 1     | Lipase                                    |                        |             |     |                  | TEDN   | 166    |
| 299         | 50              | 01/26/2010                  |                | Px        | 85025 |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                  | TEDN   | 167    |
| 300         | 50              | 01/26/2010                  |                | Px        | 85610 |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 168    |
| 301         | 50              | 01/26/2010                  |                | Px        | 85730 |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                  | TEDN   | 169    |
| 302         | 50              | 01/26/2010                  |                | Px        | 96361 |     | Facility           | 1     | Iv Infusion Hydration Each Additional Hou |                        |             |     |                  | TEDN   | 170    |
| 303         | 50              | 01/26/2010                  |                | Px        | 96374 |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbst |                        |             |     |                  | TEDN   | 171    |
| 304         | 50              | 01/26/2010                  |                | Px        | 96375 |     | Facility           | 1     | Therapeutic Injection Iv Push Each New Dr |                        |             |     |                  | TEDN   | 172    |
| 305         | 50              | 01/26/2010                  |                | Px        | 96376 |     | Facility           | 1     | Ther Proph/Dx Njx Ea Seql Iv Push Sbst/Dr |                        |             |     |                  | TEDN   | 173    |
| 306         | 50              | 01/26/2010                  |                | Px        | 99070 |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                  | TEDN   | 174    |
| 307         | 50              | 01/26/2010                  |                | Px        | 99285 |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 175    |
| 308         | 50              | 01/26/2010                  |                | Px        | 99499 |     | Facility           | 1     | Unlisted Evaluation And Management Servc  |                        |             |     |                  | TEDN   | 176    |
| 309         | 50              | 01/26/2010                  |                | Px        | A0425 |     | Facility           | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 177    |
| 310         | 50              | 01/26/2010                  |                | Px        | A0426 |     | Facility           | 1     | Als 1                                     |                        |             |     |                  | TEDN   | 178    |
| 311         | 50              | 01/26/2010                  | 02/03/2010     | Dx        | 56081 |     |                    | 1     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDI   | 179    |

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| Line Number | Time from Index | Date of Service/Admit Date | Discharge Date | Code Type | Code  | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 312         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 0389  |      |                    | 2     | Uns Septicemia                            |                        |             |     |                  | TEDI   | 179    |
| 313         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 99592 |      |                    | 3     | Severe Sepsis                             |                        |             |     |                  | TEDI   | 179    |
| 314         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 78552 |      |                    | 4     | Septic Shock                              |                        |             |     |                  | TEDI   | 179    |
| 315         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 5849  |      |                    | 5     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDI   | 179    |
| 316         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 570   |      |                    | 6     | Acute/Subacute Necrosis Liver             |                        |             |     |                  | TEDI   | 179    |
| 317         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 34831 |      |                    | 7     | Metabolic Encephalopathy                  |                        |             |     |                  | TEDI   | 179    |
| 318         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 51881 |      |                    | 8     | Respiratory Failure                       |                        |             |     |                  | TEDI   | 179    |
| 319         | 50              | 01/26/2010                 | 02/03/2010     | Dx        | 42821 |      |                    | 9     | Acute Systolic Heart Failure              |                        |             |     |                  | TEDI   | 179    |
| 320         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 5459  |      |                    | 1     | Other Periton Adhesiolysis                |                        |             |     |                  | TEDI   | 179    |
| 321         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9604  |      |                    | 2     | Insertion Endotracheal Tube               |                        |             |     |                  | TEDI   | 179    |
| 322         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9672  |      |                    | 3     | Cont Inv Mec Ven 96+ Hrs                  |                        |             |     |                  | TEDI   | 179    |
| 323         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 3891  |      |                    | 4     | Arterial Catheterization                  |                        |             |     |                  | TEDI   | 179    |
| 324         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 9904  |      |                    | 5     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 179    |
| 325         | 50              | 01/26/2010                 | 02/03/2010     | Px        | 3895  |      |                    | 6     | Ven Cath Renal Dialysis                   |                        |             |     |                  | TEDI   | 179    |
| 326         | 50              | 01/26/2010                 |                | Dx        | 5609  | Inpt | Grpprac            | 1     | Uns Intestinal Obstruction                |                        |             |     |                  | TEDN   | 158    |
| 327         | 50              | 01/26/2010                 |                | Dx        | 4011  | Inpt | Grpprac            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 158    |
| 328         | 50              | 01/26/2010                 |                | Dx        | 42731 | Inpt | Grpprac            | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 158    |
| 329         | 50              | 01/26/2010                 |                | Dx        | 2449  | Inpt | Grpprac            | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 158    |
| 330         | 50              | 01/26/2010                 |                | Px        | 99223 | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 158    |
| 331         | 51              | 01/27/2010                 |                | Dx        | 78907 | Inpt | Gensurg            | 1     | Abdominal Pain Generalized                |                        |             |     |                  | TEDN   | 180    |
| 332         | 51              | 01/27/2010                 |                | Dx        | 56081 | Inpt | Gensurg            | 2     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDN   | 180    |
| 333         | 51              | 01/27/2010                 |                | Dx        | 4460  | Inpt | Gensurg            | 3     | Polyarteritis Nodosa                      |                        |             |     |                  | TEDN   | 180    |
| 334         | 51              | 01/27/2010                 |                | Px        | 44604 | Inpt | Gensurg            | 1     | Sutr Lg Intestine 1/Mult Perforat W/O Col |                        |             |     |                  | TEDN   | 180    |
| 335         | 51              | 01/27/2010                 |                | Px        | 99232 | Inpt | Gensurg            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 181    |
| 336         | 51              | 01/27/2010                 |                | Dx        | 42761 | Inpt | Cardvasc           | 1     | Supraventricular Premature Beats          |                        |             |     |                  | TEDN   | 182    |
| 337         | 51              | 01/27/2010                 |                | Dx        | 42731 | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 182    |
| 338         | 51              | 01/27/2010                 |                | Dx        | 79431 | Inpt | Cardvasc           | 3     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 182    |
| 339         | 51              | 01/27/2010                 |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 182    |
| 340         | 51              | 01/27/2010                 |                | Dx        | 5609  | Inpt | Radio              | 1     | Uns Intestinal Obstruction                |                        |             |     |                  | TEDN   | 183    |
| 341         | 51              | 01/27/2010                 |                | Px        | 74022 | Inpt | Radio              | 1     | Radex Abd Compl Aqt Abd W/S/E/D Views 1 V |                        |             |     |                  | TEDN   | 183    |
| 342         | 51              | 01/27/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 184    |
| 343         | 51              | 01/27/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 185    |
| 344         | 51              | 01/27/2010                 |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 186    |
| 345         | 51              | 01/27/2010                 |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 186    |
| 346         | 51              | 01/27/2010                 |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 186    |
| 347         | 51              | 01/27/2010                 |                | Px        | 99233 | Inpt | Nephrr             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 186    |
| 348         | 51              | 01/27/2010                 |                | Dx        | 56081 | Inpt | Grpprac            | 1     | Intestinal Adhesions W Obstruction        |                        |             |     |                  | TEDN   | 187    |
| 349         | 51              | 01/27/2010                 |                | Px        | 00840 | Inpt | Grpprac            | 1     | Anesthesia Intraperitoneal Lower Abd W/La |                        |             |     |                  | TEDN   | 187    |

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|-------------|-----------------|----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 350         | 51              | 01/27/2010                 |                | Px        | 99223 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 188    |
| 351         | 52              | 01/28/2010                 |                | Dx        | 42761 | Inpt | Cardvasc           | 1     | Supraventricular Premature Beats          |                        |             |     |                  | TEDN   | 189    |
| 352         | 52              | 01/28/2010                 |                | Dx        | 42731 | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 189    |
| 353         | 52              | 01/28/2010                 |                | Dx        | 79431 | Inpt | Cardvasc           | 3     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 189    |
| 354         | 52              | 01/28/2010                 |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 189    |
| 355         | 52              | 01/28/2010                 |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 190    |
| 356         | 52              | 01/28/2010                 |                | Dx        | 0389  | Inpt | Radio              | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 191    |
| 357         | 52              | 01/28/2010                 |                | Dx        | 99592 | Inpt | Radio              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 191    |
| 358         | 52              | 01/28/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 191    |
| 359         | 52              | 01/28/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 192    |
| 360         | 52              | 01/28/2010                 |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 193    |
| 361         | 52              | 01/28/2010                 |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 193    |
| 362         | 52              | 01/28/2010                 |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 193    |
| 363         | 52              | 01/28/2010                 |                | Px        | 99233 | Inpt | Nephrr             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 193    |
| 364         | 52              | 01/28/2010                 |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 194    |
| 365         | 52              | 01/28/2010                 |                | Dx        | 2752  | Inpt | Grpract            | 2     | Disorders Magnesium Metabolism            |                        |             |     |                  | TEDN   | 194    |
| 366         | 52              | 01/28/2010                 |                | Dx        | 27541 | Inpt | Grpract            | 3     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 194    |
| 367         | 52              | 01/28/2010                 |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 194    |
| 368         | 52              | 01/28/2010                 |                | Px        | 93010 | Inpt | Grpract            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 195    |
| 369         | 52              | 01/28/2010                 |                | Px        | 31500 | Inpt | Grpract            | 1     | Intubation Endotracheal Emergency Procedu |                        |             |     |                  | TEDN   | 196    |
| 370         | 52              | 01/28/2010                 |                | Px        | 99291 | Inpt | Grpract            | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 197    |
| 371         | 53              | 01/29/2010                 |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 198    |
| 372         | 53              | 01/29/2010                 |                | Dx        | 7905  | Inpt | Cardvasc           | 2     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 198    |
| 373         | 53              | 01/29/2010                 |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 198    |
| 374         | 53              | 01/29/2010                 |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 199    |
| 375         | 53              | 01/29/2010                 |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 200    |
| 376         | 53              | 01/29/2010                 |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 200    |
| 377         | 53              | 01/29/2010                 |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 200    |
| 378         | 53              | 01/29/2010                 |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 200    |
| 379         | 53              | 01/29/2010                 |                | Px        | 36620 | Inpt | Pulmo              | 1     | Artl Cathj/Cannulj Mntr/Transfusion Spx P |                        |             |     |                  | TEDN   | 200    |
| 380         | 53              | 01/29/2010                 |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 201    |
| 381         | 53              | 01/29/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 201    |
| 382         | 53              | 01/29/2010                 |                | Dx        | 5854  | Inpt | Nephrr             | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 202    |
| 383         | 53              | 01/29/2010                 |                | Dx        | 5849  | Inpt | Nephrr             | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 202    |
| 384         | 53              | 01/29/2010                 |                | Dx        | 4589  | Inpt | Nephrr             | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 202    |
| 385         | 53              | 01/29/2010                 |                | Px        | 36556 | Inpt | Nephrr             | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 202    |
| 386         | 53              | 01/29/2010                 |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 203    |
| 387         | 53              | 01/29/2010                 |                | Dx        | 2851  | Inpt | Grpract            | 2     | Acute Posthemorrhagic Anemia              |                        |             |     |                  | TEDN   | 203    |

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|-------------|-----------------|-----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 388         | 53              | 01/29/2010                  |                | Px        | 99231 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 203    |
| 389         | 54              | 01/30/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 204    |
| 390         | 54              | 01/30/2010                  |                | Dx        | 7905  | Inpt | Cardvasc           | 2     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 204    |
| 391         | 54              | 01/30/2010                  |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 204    |
| 392         | 54              | 01/30/2010                  |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 205    |
| 393         | 54              | 01/30/2010                  |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 205    |
| 394         | 54              | 01/30/2010                  |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 205    |
| 395         | 54              | 01/30/2010                  |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 205    |
| 396         | 54              | 01/30/2010                  |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 205    |
| 397         | 54              | 01/30/2010                  |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 206    |
| 398         | 54              | 01/30/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 206    |
| 399         | 54              | 01/30/2010                  |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 207    |
| 400         | 54              | 01/30/2010                  |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 207    |
| 401         | 54              | 01/30/2010                  |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 207    |
| 402         | 54              | 01/30/2010                  |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 207    |
| 403         | 54              | 01/30/2010                  |                | Dx        | 2449  | Inpt | Grpract            | 1     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 208    |
| 404         | 54              | 01/30/2010                  |                | Dx        | 2851  | Inpt | Grpract            | 2     | Acute Posthemorrhagic Anemia              |                        |             |     |                  | TEDN   | 208    |
| 405         | 54              | 01/30/2010                  |                | Px        | 99231 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 208    |
| 406         | 55              | 01/31/2010                  |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 209    |
| 407         | 55              | 01/31/2010                  |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 209    |
| 408         | 55              | 01/31/2010                  |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 209    |
| 409         | 55              | 01/31/2010                  |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 209    |
| 410         | 55              | 01/31/2010                  |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 209    |
| 411         | 55              | 01/31/2010                  |                | Dx        | 43491 | Inpt | Radio              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 210    |
| 412         | 55              | 01/31/2010                  |                | Px        | 70450 | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 210    |
| 413         | 55              | 01/31/2010                  |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 211    |
| 414         | 55              | 01/31/2010                  |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 212    |
| 415         | 55              | 01/31/2010                  |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 212    |
| 416         | 55              | 01/31/2010                  |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 212    |
| 417         | 55              | 01/31/2010                  |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 212    |
| 418         | 55              | 01/31/2010                  |                | Dx        | 34830 | Inpt | Grpract            | 1     | Encephalopathy Unspecified                |                        |             |     |                  | TEDN   | 213    |
| 419         | 55              | 01/31/2010                  |                | Px        | 99223 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 213    |
| 420         | 55              | 01/31/2010                  |                | Px        | 95822 | Inpt | Grpract            | 1     | Electroencephalogram Rec Coma/Sleep Only  |                        |             |     |                  | TEDN   | 214    |
| 421         | 56              | 02/01/2010                  |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 215    |
| 422         | 56              | 02/01/2010                  |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 215    |
| 423         | 56              | 02/01/2010                  |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 216    |
| 424         | 56              | 02/01/2010                  |                | Dx        | 43491 | Inpt | Neuro              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 217    |
| 425         | 56              | 02/01/2010                  |                | Dx        | 34591 | Inpt | Neuro              | 2     | Uns Epilepsy W Intract Epilepsy           |                        |             |     |                  | TEDN   | 217    |

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|-------------|-----------------|----------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 426         | 56              | 02/01/2010                 |                | Px        | 99223 | Inpt | Neuro              | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 217    |
| 427         | 56              | 02/01/2010                 |                | Dx        | 51881 | Inpt | Pulmo              | 1     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 218    |
| 428         | 56              | 02/01/2010                 |                | Dx        | 99592 | Inpt | Pulmo              | 2     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 218    |
| 429         | 56              | 02/01/2010                 |                | Dx        | 4589  | Inpt | Pulmo              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 218    |
| 430         | 56              | 02/01/2010                 |                | Dx        | 4829  | Inpt | Pulmo              | 4     | Uns Bacterial Pneumonia                   |                        |             |     |                  | TEDN   | 218    |
| 431         | 56              | 02/01/2010                 |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 218    |
| 432         | 56              | 02/01/2010                 |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 219    |
| 433         | 56              | 02/01/2010                 |                | Dx        | 2774  | Inpt | Radio              | 2     | Disorders Bilirubin Excretion             |                        |             |     |                  | TEDN   | 219    |
| 434         | 56              | 02/01/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 219    |
| 435         | 56              | 02/01/2010                 |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 220    |
| 436         | 56              | 02/01/2010                 |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 221    |
| 437         | 56              | 02/01/2010                 |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 221    |
| 438         | 56              | 02/01/2010                 |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 221    |
| 439         | 56              | 02/01/2010                 |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 221    |
| 440         | 56              | 02/01/2010                 |                | Dx        | 5679  | Inpt | Grppract           | 1     | Uns Peritonitis                           |                        |             |     |                  | TEDN   | 222    |
| 441         | 56              | 02/01/2010                 |                | Px        | 99223 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 222    |
| 442         | 57              | 02/02/2010                 |                | Dx        | 43491 | Inpt | Neuro              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 223    |
| 443         | 57              | 02/02/2010                 |                | Dx        | 34591 | Inpt | Neuro              | 2     | Uns Epilepsy W Intract Epilepsy           |                        |             |     |                  | TEDN   | 223    |
| 444         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Neuro              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 223    |
| 445         | 57              | 02/02/2010                 |                | Dx        | V5882 | Inpt | Radio              | 1     | Fitting/Adjust Nonvascular Cath           |                        |             |     |                  | TEDN   | 224    |
| 446         | 57              | 02/02/2010                 |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 224    |
| 447         | 57              | 02/02/2010                 |                | Dx        | 5854  | Inpt | Nephr              | 1     | Chronic Kidney Disease Stage Iv           |                        |             |     |                  | TEDN   | 225    |
| 448         | 57              | 02/02/2010                 |                | Dx        | 5849  | Inpt | Nephr              | 2     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 225    |
| 449         | 57              | 02/02/2010                 |                | Dx        | 4589  | Inpt | Nephr              | 3     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 225    |
| 450         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Nephr              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 225    |
| 451         | 57              | 02/02/2010                 |                | Dx        | 5679  | Inpt | Grppract           | 1     | Uns Peritonitis                           |                        |             |     |                  | TEDN   | 226    |
| 452         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 226    |
| 453         | 57              | 02/02/2010                 |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 227    |

End of Profile



Patient ID: SLD-0126

Age: 81 Gender: F Indexdate: 06/23/2012 Event Date: 07/17/2013 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation             | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 1           | -362            | 06/27/2011                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 1      |
| 2           | -347            | 07/12/2011                     |                | Dx        | 4512        |     | Intmed             | 1     | Uns Phlebitis Lower Limbs                 |                        |             |     |                              | TEDN   | 2      |
| 3           | -347            | 07/12/2011                     |                | Px        | 99220       |     | Intmed             | 1     | Initial Observation Care/Day High Severit |                        |             |     |                              | TEDN   | 2      |
| 4           | -347            | 07/12/2011                     |                | Dx        | 4928        |     | Radio              | 1     | Other Emphysema                           |                        |             |     |                              | TEDN   | 3      |
| 5           | -347            | 07/12/2011                     |                | Px        | 71020       |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                              | TEDN   | 3      |
| 6           | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Radio              | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 4      |
| 7           | -347            | 07/12/2011                     |                | Dx        | 45342       |     | Radio              | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 4      |
| 8           | -347            | 07/12/2011                     |                | Dx        | 45119       |     | Radio              | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 4      |
| 9           | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Radio              | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 4      |
| 10          | -347            | 07/12/2011                     |                | Px        | 93970       |     | Radio              | 1     | Dup-Scan Xtr Veins Complete Bilateral Stu |                        |             |     |                              | TEDN   | 4      |
| 11          | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Facility           | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 5      |
| 12          | -347            | 07/12/2011                     |                | Dx        | 45342       |     | Facility           | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 5      |
| 13          | -347            | 07/12/2011                     |                | Dx        | 45119       |     | Facility           | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 5      |
| 14          | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Facility           | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 5      |
| 15          | -347            | 07/12/2011                     |                | Dx        | 71690       |     | Facility           | 5     | Uns Arthropathy Site Uns                  |                        |             |     |                              | TEDN   | 5      |
| 16          | -347            | 07/12/2011                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension        |                        |             |     |                              | TEDN   | 5      |
| 17          | -347            | 07/12/2011                     |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                              | TEDN   | 5      |
| 18          | -347            | 07/12/2011                     |                | Dx        | 78039       |     | Facility           | 8     | Other Convulsions                         |                        |             |     |                              | TEDN   | 5      |
| 19          | -347            | 07/12/2011                     |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                              | TEDN   | 5      |
| 20          | -347            | 07/12/2011                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                              | TEDN   | 6      |
| 21          | -347            | 07/12/2011                     |                | Px        | 84484       |     | Facility           | 1     | Troponin Quantitative                     |                        |             |     |                              | TEDN   | 7      |
| 22          | -347            | 07/12/2011                     |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                              | TEDN   | 8      |
| 23          | -347            | 07/12/2011                     |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 9      |
| 24          | -347            | 07/12/2011                     |                | Px        | 85730       |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                              | TEDN   | 10     |
| 25          | -347            | 07/12/2011                     |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                              | TEDN   | 11     |
| 26          | -347            | 07/12/2011                     |                | Px        | 93970       |     | Facility           | 1     | Dup-Scan Xtr Veins Complete Bilateral Stu |                        |             |     |                              | TEDN   | 12     |
| 27          | -347            | 07/12/2011                     |                | Px        | 96361       |     | Facility           | 1     | Iv Infusion Hydration Each Additional Hou |                        |             |     |                              | TEDN   | 13     |
| 28          | -347            | 07/12/2011                     |                | Px        | 96365       |     | Facility           | 1     | Iv Infusion Therapy/Prophylaxis /Dx 1st T |                        |             |     |                              | TEDN   | 14     |
| 29          | -347            | 07/12/2011                     |                | Px        | 96372       |     | Facility           | 1     | Therapeutic Prophylactic/Dx Injection Sub |                        |             |     |                              | TEDN   | 15     |
| 30          | -347            | 07/12/2011                     |                | Px        | 96375       |     | Facility           | 1     | Therapeutic Injection Iv Push Each New Dr |                        |             |     |                              | TEDN   | 16     |
| 31          | -347            | 07/12/2011                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                              | TEDN   | 17     |
| 32          | -347            | 07/12/2011                     |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                              | TEDN   | 18     |
| 33          | -347            | 07/12/2011                     |                | Dx        | 78650       |     | Grppract           | 1     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 19     |
| 34          | -347            | 07/12/2011                     |                | Dx        | 6826        |     | Grppract           | 2     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 19     |
| 35          | -347            | 07/12/2011                     |                | Dx        | 45340       |     | Grppract           | 3     | Ac Emb/Throm Uns Deep Ves Lower Ext       |                        |             |     |                              | TEDN   | 19     |
| 36          | -347            | 07/12/2011                     |                | Px        | 93010       |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds l&r Only   |                        |             |     |                              | TEDN   | 19     |
| 37          | -347            | 07/12/2011                     |                | Px        | 99285       |     | Grppract           | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                              | TEDN   | 20     |
| 38          | -346            | 07/13/2011                     |                | Dx        | 6826        |     | Facility           | 1     | Cellulitis/Abscess Leg Ex Foot            |                        |             |     |                              | TEDN   | 25     |
| 39          | -346            | 07/13/2011                     |                | Dx        | 45342       |     | Facility           | 2     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 25     |
| 40          | -346            | 07/13/2011                     |                | Dx        | 45119       |     | Facility           | 3     | Phlebitis Oth Deep Vessels L Limbs        |                        |             |     |                              | TEDN   | 25     |
| 41          | -346            | 07/13/2011                     |                | Dx        | 78650       |     | Facility           | 4     | Unspec Chest Pain                         |                        |             |     |                              | TEDN   | 25     |
| 42          | -346            | 07/13/2011                     |                | Dx        | 71690       |     | Facility           | 5     | Uns Arthropathy Site Uns                  |                        |             |     |                              | TEDN   | 25     |
| 43          | -346            | 07/13/2011                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension        |                        |             |     |                              | TEDN   | 25     |
| 44          | -346            | 07/13/2011                     |                | Dx        | 2720        |     | Facility           | 7     | Pure Hypercholesterolemia                 |                        |             |     |                              | TEDN   | 25     |
| 45          | -346            | 07/13/2011                     |                | Dx        | 78039       |     | Facility           | 8     | Other Convulsions                         |                        |             |     |                              | TEDN   | 25     |
| 46          | -346            | 07/13/2011                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                              | TEDN   | 25     |

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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation             | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 47          | -346            | 07/13/2011                     |                | Px        | 85025       |      | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb |                        |             |     |                              | TEDN   | 26     |
| 48          | -346            | 07/13/2011                     |                | Px        | 99070       |      | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                        |             |     |                              | TEDN   | 27     |
| 49          | -346            | 07/13/2011                     |                | Rx        | 42043014105 |      |                    |       |                                           | Cephalexin             | 10          | 30  | Capsule (Hard, Soft, Etc.)   | PDTS   | 21     |
| 50          | -346            | 07/13/2011                     |                | Rx        | 00555083305 |      |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                       | PDTS   | 22     |
| 51          | -346            | 07/13/2011                     |                | Rx        | 00781311968 |      |                    |       |                                           | Enoxaparin Sodium      | 7           | 11  | Disposable Syringe (MI)      | PDTS   | 23     |
| 52          | -346            | 07/13/2011                     |                | Rx        | 00378520905 |      |                    |       |                                           | Amlodipine Besylate    | 30          | 30  | Tablet                       | PDTS   | 24     |
| 53          | -345            | 07/14/2011                     |                | Dx        | 45111       |      | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 28     |
| 54          | -345            | 07/14/2011                     |                | Dx        | 7197        |      | Intmed             | 2     | Difficulty In Walking                     |                        |             |     |                              | TEDN   | 28     |
| 55          | -345            | 07/14/2011                     |                | Dx        | 78079       |      | Intmed             | 3     | Other Malaise And Fatigue                 |                        |             |     |                              | TEDN   | 28     |
| 56          | -345            | 07/14/2011                     |                | Px        | G0180       |      | Intmed             | 1     | Md Certification Hha Patient              |                        |             |     |                              | TEDN   | 28     |
| 57          | -337            | 07/22/2011                     |                | Dx        | 5693        |      | Gp                 | 1     | Hemorrhage Rectum/Anus                    |                        |             |     |                              | TEDN   | 30     |
| 58          | -337            | 07/22/2011                     |                | Dx        | 59970       |      | Gp                 | 2     | Hematuria Unspecified                     |                        |             |     |                              | TEDN   | 30     |
| 59          | -337            | 07/22/2011                     |                | Dx        | 45342       |      | Gp                 | 3     | Ac Emb/Thr Dist Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 30     |
| 60          | -337            | 07/22/2011                     |                | Dx        | 2869        |      | Gp                 | 4     | Oth/Uns Coagulation Defects               |                        |             |     |                              | TEDN   | 30     |
| 61          | -337            | 07/22/2011                     |                | Px        | 99291       |      | Gp                 | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                              | TEDN   | 30     |
| 62          | -337            | 07/22/2011                     |                | Dx        | 3489        | Inpt | Radio              | 1     | Unspecified Condition Of Brain            |                        |             |     |                              | TEDN   | 29     |
| 63          | -337            | 07/22/2011                     |                | Dx        | 7840        | Inpt | Radio              | 2     | Headache                                  |                        |             |     |                              | TEDN   | 29     |
| 64          | -337            | 07/22/2011                     |                | Dx        | 2989        | Inpt | Radio              | 3     | Unspecified Psychosis                     |                        |             |     |                              | TEDN   | 29     |
| 65          | -337            | 07/22/2011                     |                | Px        | 70450       | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                              | TEDN   | 29     |
| 66          | -337            | 07/22/2011                     |                | Dx        | 5781        | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                              | TEDN   | 31     |
| 67          | -337            | 07/22/2011                     |                | Dx        | 56210       | Inpt | Gastro             | 2     | Diverticulosis Colon                      |                        |             |     |                              | TEDN   | 31     |
| 68          | -337            | 07/22/2011                     |                | Px        | 99222       | Inpt | Gastro             | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                              | TEDN   | 31     |
| 69          | -337            | 07/22/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 32     |
| 70          | -337            | 07/22/2011                     |                | Px        | 99223       | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                              | TEDN   | 32     |
| 71          | -336            | 07/23/2011                     |                | Dx        | 5781        | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                              | TEDN   | 33     |
| 72          | -336            | 07/23/2011                     |                | Dx        | 56210       | Inpt | Gastro             | 2     | Diverticulosis Colon                      |                        |             |     |                              | TEDN   | 33     |
| 73          | -336            | 07/23/2011                     |                | Px        | 45378       | Inpt | Gastro             | 1     | Colonoscopy Flx Dx W/Wo Collj Specimens   |                        |             |     |                              | TEDN   | 33     |
| 74          | -336            | 07/23/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 34     |
| 75          | -336            | 07/23/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 34     |
| 76          | -335            | 07/24/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 35     |
| 77          | -335            | 07/24/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 35     |
| 78          | -334            | 07/25/2011                     |                | Dx        | 56212       | Inpt | Gensurg            | 1     | Diverticulosis Colon W Hemorrhage         |                        |             |     |                              | TEDN   | 36     |
| 79          | -334            | 07/25/2011                     |                | Dx        | 4536        | Inpt | Gensurg            | 2     | Emb/Throm Superficial Lower Ext           |                        |             |     |                              | TEDN   | 36     |
| 80          | -334            | 07/25/2011                     |                | Dx        | 45351       | Inpt | Gensurg            | 3     | Ch Emb/Thr Prox Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 36     |
| 81          | -334            | 07/25/2011                     |                | Dx        | 59970       | Inpt | Gensurg            | 4     | Hematuria Unspecified                     |                        |             |     |                              | TEDN   | 36     |
| 82          | -334            | 07/25/2011                     |                | Px        | 93971       | Inpt | Gensurg            | 1     | Dup-Scan Xtr Veins Unilateral/Limited Stu |                        |             |     |                              | TEDN   | 36     |
| 83          | -334            | 07/25/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 37     |
| 84          | -334            | 07/25/2011                     |                | Px        | 99232       | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                              | TEDN   | 37     |
| 85          | -333            | 07/26/2011                     |                | Dx        | 5789        | Inpt | Intmed             | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                              | TEDN   | 38     |
| 86          | -333            | 07/26/2011                     |                | Px        | 99238       | Inpt | Intmed             | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                              | TEDN   | 38     |
| 87          | -323            | 08/05/2011                     |                | Rx        | 55111015810 |      |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 39     |
| 88          | -305            | 08/23/2011                     |                | Dx        | 79902       |      | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 40     |
| 89          | -305            | 08/23/2011                     |                | Px        | E0431       |      | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 40     |
| 90          | -305            | 08/23/2011                     |                | Px        | E1390       |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 41     |
| 91          | -304            | 08/24/2011                     |                | Rx        | 00054001725 |      |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 42     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|--------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 92          | -303            | 08/25/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 43     |
| 93          | -289            | 09/08/2011                     |                | Rx        | 00093714618 |     |                    |       |                                            | Azithromycin           | 5           | 6   | Tablet                       | PDTS   | 44     |
| 94          | -274            | 09/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 45     |
| 95          | -274            | 09/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 45     |
| 96          | -274            | 09/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 46     |
| 97          | -264            | 10/03/2011                     |                | Rx        | 33332001101 |     |                    |       |                                            | Afluria 2011-2012 (Pf) | 1           | 1   | Disposable Syringe (MI)      | PDTS   | 47     |
| 98          | -263            | 10/04/2011                     |                | Rx        | 55111015810 |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 48     |
| 99          | -261            | 10/06/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 49     |
| 100         | -260            | 10/07/2011                     |                | Rx        | 63304062210 |     |                    |       |                                            | Atenolol               | 90          | 180 | Tablet                       | PDTS   | 50     |
| 101         | -256            | 10/11/2011                     |                | Rx        | 68180075103 |     |                    |       |                                            | Amlodipine Besylate    | 90          | 90  | Tablet                       | PDTS   | 51     |
| 102         | -244            | 10/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 52     |
| 103         | -244            | 10/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 52     |
| 104         | -244            | 10/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 53     |
| 105         | -243            | 10/24/2011                     |                | Dx        | 56989       |     | Radio              | 1     | Other Disorders Intestines                 |                        |             |     |                              | TEDN   | 54     |
| 106         | -243            | 10/24/2011                     |                | Dx        | 78900       |     | Radio              | 2     | Abdominal Pain Uns Site                    |                        |             |     |                              | TEDN   | 54     |
| 107         | -243            | 10/24/2011                     |                | Px        | 74177       |     | Radio              | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                              | TEDN   | 54     |
| 108         | -243            | 10/24/2011                     |                | Dx        | 78901       |     | Gp                 | 1     | Abdom Pain R Upper Quad                    |                        |             |     |                              | TEDN   | 55     |
| 109         | -243            | 10/24/2011                     |                | Dx        | 78702       |     | Gp                 | 2     | Nausea Alone                               |                        |             |     |                              | TEDN   | 55     |
| 110         | -243            | 10/24/2011                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se  |                        |             |     |                              | TEDN   | 55     |
| 111         | -243            | 10/24/2011                     |                | Dx        | 78901       |     | Facility           | 1     | Abdom Pain R Upper Quad                    |                        |             |     |                              | TEDN   | 56     |
| 112         | -243            | 10/24/2011                     |                | Dx        | 78702       |     | Facility           | 2     | Nausea Alone                               |                        |             |     |                              | TEDN   | 56     |
| 113         | -243            | 10/24/2011                     |                | Dx        | 7962        |     | Facility           | 3     | Elevated Bp Reading Wo Htn Dx              |                        |             |     |                              | TEDN   | 56     |
| 114         | -243            | 10/24/2011                     |                | Dx        | 2720        |     | Facility           | 4     | Pure Hypercholesterolemia                  |                        |             |     |                              | TEDN   | 56     |
| 115         | -243            | 10/24/2011                     |                | Dx        | 7102        |     | Facility           | 5     | Sicca Syndrome                             |                        |             |     |                              | TEDN   | 56     |
| 116         | -243            | 10/24/2011                     |                | Dx        | 7291        |     | Facility           | 6     | Uns Myalgia/Myositis                       |                        |             |     |                              | TEDN   | 56     |
| 117         | -243            | 10/24/2011                     |                | Dx        | 33829       |     | Facility           | 7     | Other Chronic Pain                         |                        |             |     |                              | TEDN   | 56     |
| 118         | -243            | 10/24/2011                     |                | Dx        | V1251       |     | Facility           | 8     | History Venous Thrombosis/Embolism         |                        |             |     |                              | TEDN   | 56     |
| 119         | -243            | 10/24/2011                     |                | Px        | 74177       |     | Facility           | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                              | TEDN   | 56     |
| 120         | -243            | 10/24/2011                     |                | Px        | 80053       |     | Facility           | 1     | Comprehensive Metabolic Panel              |                        |             |     |                              | TEDN   | 57     |
| 121         | -243            | 10/24/2011                     |                | Px        | 81001       |     | Facility           | 1     | Urnl Dip Stick/Tablet Reagent Auto Micro   |                        |             |     |                              | TEDN   | 58     |
| 122         | -243            | 10/24/2011                     |                | Px        | 83690       |     | Facility           | 1     | Lipase                                     |                        |             |     |                              | TEDN   | 59     |
| 123         | -243            | 10/24/2011                     |                | Px        | 85025       |     | Facility           | 1     | Blood Count Complete Auto&auto Diffrntl Wb |                        |             |     |                              | TEDN   | 60     |
| 124         | -243            | 10/24/2011                     |                | Px        | 96374       |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbst  |                        |             |     |                              | TEDN   | 61     |
| 125         | -243            | 10/24/2011                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above     |                        |             |     |                              | TEDN   | 62     |
| 126         | -243            | 10/24/2011                     |                | Px        | 99284       |     | Facility           | 1     | Emergency Department Visit High/Urgent Se  |                        |             |     |                              | TEDN   | 63     |
| 127         | -235            | 11/01/2011                     |                | Dx        | 4019        |     | Patho              | 1     | Unspecified Essential Hypertension         |                        |             |     |                              | TEDN   | 64     |
| 128         | -235            | 11/01/2011                     |                | Dx        | 2859        |     | Patho              | 2     | Anemia Unspecified                         |                        |             |     |                              | TEDN   | 64     |
| 129         | -235            | 11/01/2011                     |                | Dx        | 45340       |     | Patho              | 3     | Ac Emb/Throm Uns Deep Ves Lower Ext        |                        |             |     |                              | TEDN   | 64     |
| 130         | -235            | 11/01/2011                     |                | Px        | 85390       |     | Patho              | 1     | Fibrinolysins/Coagulopathy Screen Interp&  |                        |             |     |                              | TEDN   | 64     |
| 131         | -223            | 11/13/2011                     |                | Rx        | 68645028254 |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 65     |
| 132         | -219            | 11/17/2011                     |                | Rx        | 00054001725 |     |                    |       |                                            | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 66     |
| 133         | -213            | 11/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 67     |
| 134         | -213            | 11/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                              | TEDN   | 67     |
| 135         | -213            | 11/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                              | TEDN   | 68     |
| 136         | -210            | 11/26/2011                     |                | Rx        | 55111015810 |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 69     |
| 137         | -183            | 12/23/2011                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                              | TEDN   | 70     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 138         | -183            | 12/23/2011                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 70     |
| 139         | -183            | 12/23/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 71     |
| 140         | -171            | 01/04/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 72     |
| 141         | -157            | 01/18/2012                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr              | 30          | 30  | Tablet                       | PDTS   | 73     |
| 142         | -152            | 01/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 74     |
| 143         | -152            | 01/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 74     |
| 144         | -152            | 01/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 75     |
| 145         | -144            | 01/31/2012                     |                | Rx        | 00054001725 |     |                    |       |                                           | Prednisone                  | 90          | 90  | Tablet                       | PDTS   | 76     |
| 146         | -127            | 02/17/2012                     |                | Dx        | 7881        |     | Intmed             | 1     | Dysuria                                   |                             |             |     |                              | TEDN   | 77     |
| 147         | -127            | 02/17/2012                     |                | Dx        | 78097       |     | Intmed             | 2     | Altered Mental Status                     |                             |             |     |                              | TEDN   | 77     |
| 148         | -127            | 02/17/2012                     |                | Px        | 81002       |     | Intmed             | 1     | Urnl Dip Stick/Tablet Rgnt Non-Auto W/O   |                             |             |     |                              | TEDN   | 77     |
| 149         | -127            | 02/17/2012                     |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 78     |
| 150         | -121            | 02/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 79     |
| 151         | -121            | 02/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 79     |
| 152         | -121            | 02/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 80     |
| 153         | -110            | 03/05/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 81     |
| 154         | -92             | 03/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 82     |
| 155         | -92             | 03/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 82     |
| 156         | -92             | 03/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 83     |
| 157         | -83             | 04/01/2012                     |                | Rx        | 00054001729 |     |                    |       |                                           | Prednisone                  | 90          | 90  | Tablet                       | PDTS   | 84     |
| 158         | -81             | 04/03/2012                     |                | Dx        | 37515       |     | Oph                | 1     | Uns Tear Film Insufficiency               |                             |             |     |                              | TEDN   | 85     |
| 159         | -81             | 04/03/2012                     |                | Dx        | 36501       |     | Oph                | 2     | Op Angle Borderline Low Risk              |                             |             |     |                              | TEDN   | 85     |
| 160         | -81             | 04/03/2012                     |                | Dx        | 36257       |     | Oph                | 3     | Drusen (Degenerative) Of Retina           |                             |             |     |                              | TEDN   | 85     |
| 161         | -81             | 04/03/2012                     |                | Px        | 76514       |     | Oph                | 1     | Ophthalmic Us Dx Corneal Pachymetry Uni/B |                             |             |     |                              | TEDN   | 85     |
| 162         | -81             | 04/03/2012                     |                | Px        | 92014       |     | Oph                | 1     | Ophth Medical Xm&eval Comprhnsv Estab Pt  |                             |             |     |                              | TEDN   | 86     |
| 163         | -81             | 04/03/2012                     |                | Px        | 92250       |     | Oph                | 1     | Fundus Photography W/Interpretation & Rep |                             |             |     |                              | TEDN   | 87     |
| 164         | -73             | 04/11/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 88     |
| 165         | -61             | 04/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 90     |
| 166         | -61             | 04/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 90     |
| 167         | -61             | 04/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 91     |
| 168         | -61             | 04/23/2012                     |                | Rx        | 68180075103 |     |                    |       |                                           | Amlodipine Besylate         | 90          | 90  | Tablet                       | PDTS   | 89     |
| 169         | -57             | 04/27/2012                     |                | Dx        | 7102        |     | Intmed             | 1     | Sicca Syndrome                            |                             |             |     |                              | TEDN   | 92     |
| 170         | -57             | 04/27/2012                     |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 92     |
| 171         | -53             | 05/01/2012                     |                | Rx        | 65862001705 |     |                    |       |                                           | Amoxicillin                 | 7           | 30  | Capsule (Hard, Soft, Etc.)   | PDTS   | 93     |
| 172         | -31             | 05/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 94     |
| 173         | -31             | 05/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 94     |
| 174         | -31             | 05/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 95     |
| 175         | -28             | 05/26/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 96     |
| 176         | -19             | 06/04/2012                     |                | Dx        | 38021       |     | Intmed             | 1     | Cholesteatoma External Ear                |                             |             |     |                              | TEDN   | 98     |
| 177         | -19             | 06/04/2012                     |                | Dx        | 7804        |     | Intmed             | 2     | Dizziness And Giddiness                   |                             |             |     |                              | TEDN   | 98     |
| 178         | -19             | 06/04/2012                     |                | Dx        | 38870       |     | Intmed             | 3     | Otalgia Unspecified                       |                             |             |     |                              | TEDN   | 98     |
| 179         | -19             | 06/04/2012                     |                | Px        | 99214       |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 98     |
| 180         | -19             | 06/04/2012                     |                | Rx        | 24208063110 |     |                    |       |                                           | Neomycin-Polymyxin-Hydrocor | 16          | 10  | Solution, Non-Oral           | PDTS   | 97     |
| 181         | -18             | 06/05/2012                     |                | Dx        | 42731       |     | Gp                 | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 99     |
| 182         | -18             | 06/05/2012                     |                | Dx        | 7840        |     | Gp                 | 2     | Headache                                  |                             |             |     |                              | TEDN   | 99     |
| 183         | -18             | 06/05/2012                     |                | Dx        | 78079       |     | Gp                 | 3     | Other Malaise And Fatigue                 |                             |             |     |                              | TEDN   | 99     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 184         | -18             | 06/05/2012                     |                | Dx        | 4019  |      | Gp                 | 4     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 99     |
| 185         | -18             | 06/05/2012                     |                | Px        | 93010 |      | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 99     |
| 186         | -18             | 06/05/2012                     |                | Px        | 99285 |      | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 100    |
| 187         | -18             | 06/05/2012                     |                | Dx        | 7840  |      | Radio              | 1     | Headache                                  |                        |             |     |                  | TEDN   | 101    |
| 188         | -18             | 06/05/2012                     |                | Px        | 70450 |      | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 101    |
| 189         | -17             | 06/06/2012                     |                | Dx        | 43330 |      | Gensurg            | 1     | Occlus Mult Bilat Precer Art Wo Inf       |                        |             |     |                  | TEDN   | 104    |
| 190         | -17             | 06/06/2012                     |                | Px        | 93880 |      | Gensurg            | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                        |             |     |                  | TEDN   | 104    |
| 191         | -17             | 06/06/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 102    |
| 192         | -17             | 06/06/2012                     |                | Dx        | 4011  | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 102    |
| 193         | -17             | 06/06/2012                     |                | Dx        | 2720  | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                        |             |     |                  | TEDN   | 102    |
| 194         | -17             | 06/06/2012                     |                | Dx        | 5789  | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 102    |
| 195         | -17             | 06/06/2012                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Thrc R-T 2d W/Wom-Mode Compl Spec&c  |                        |             |     |                  | TEDN   | 102    |
| 196         | -17             | 06/06/2012                     |                | Px        | 99223 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 103    |
| 197         | -17             | 06/06/2012                     |                | Dx        | 43491 | Inpt | Cardvasc           | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 105    |
| 198         | -17             | 06/06/2012                     |                | Dx        | 42732 | Inpt | Cardvasc           | 2     | Atrial Flutter                            |                        |             |     |                  | TEDN   | 105    |
| 199         | -17             | 06/06/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 105    |
| 200         | -17             | 06/06/2012                     |                | Dx        | 72989 | Inpt | Cardvasc           | 4     | Oth Musculoskeletal Sympt Limbs           |                        |             |     |                  | TEDN   | 105    |
| 201         | -17             | 06/06/2012                     |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 105    |
| 202         | -17             | 06/06/2012                     |                | Dx        | 4359  | Inpt | Intmed             | 1     | Uns Transient Cerebral Ischemia           |                        |             |     |                  | TEDN   | 106    |
| 203         | -17             | 06/06/2012                     |                | Dx        | 42732 | Inpt | Intmed             | 2     | Atrial Flutter                            |                        |             |     |                  | TEDN   | 106    |
| 204         | -17             | 06/06/2012                     |                | Px        | 99223 | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 106    |
| 205         | -17             | 06/06/2012                     |                | Dx        | 7220  | Inpt | Radio              | 1     | Displaced Cervical Intervert Disc         |                        |             |     |                  | TEDN   | 107    |
| 206         | -17             | 06/06/2012                     |                | Dx        | 7224  | Inpt | Radio              | 2     | Degeneration Cervical Iv Disc             |                        |             |     |                  | TEDN   | 107    |
| 207         | -17             | 06/06/2012                     |                | Px        | 72141 | Inpt | Radio              | 1     | Mri Spinal Canal Cervical W/O Contrast Ma |                        |             |     |                  | TEDN   | 107    |
| 208         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 108    |
| 209         | -16             | 06/07/2012                     |                | Px        | 93312 | Inpt | Cardvasc           | 1     | Ecg Transesophag R-T 2d W/Prb Img Acquisj |                        |             |     |                  | TEDN   | 108    |
| 210         | -16             | 06/07/2012                     |                | Px        | 93320 | Inpt | Cardvasc           | 1     | Doppler Echocard Pulse Wave W/Spectral Di |                        |             |     |                  | TEDN   | 109    |
| 211         | -16             | 06/07/2012                     |                | Px        | 93325 | Inpt | Cardvasc           | 1     | Dop Echocard Color Flow Velocity Mapping  |                        |             |     |                  | TEDN   | 110    |
| 212         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 111    |
| 213         | -16             | 06/07/2012                     |                | Dx        | 4011  | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 111    |
| 214         | -16             | 06/07/2012                     |                | Dx        | 2720  | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                        |             |     |                  | TEDN   | 111    |
| 215         | -16             | 06/07/2012                     |                | Dx        | 5789  | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 111    |
| 216         | -16             | 06/07/2012                     |                | Px        | 92960 | Inpt | Cardvasc           | 1     | Cardioversion Elective Arrhythmia Externa |                        |             |     |                  | TEDN   | 111    |
| 217         | -16             | 06/07/2012                     |                | Px        | 99231 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 112    |
| 218         | -16             | 06/07/2012                     |                | Dx        | 42731 | Inpt | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 113    |
| 219         | -16             | 06/07/2012                     |                | Dx        | 436   | Inpt | Intmed             | 2     | Acute Ill Defined Cv Disease              |                        |             |     |                  | TEDN   | 113    |
| 220         | -16             | 06/07/2012                     |                | Dx        | V5861 | Inpt | Intmed             | 3     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 113    |
| 221         | -16             | 06/07/2012                     |                | Px        | 99232 | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 113    |
| 222         | -16             | 06/07/2012                     |                | Dx        | 43491 | Inpt | Radio              | 1     | Uns Cer Artery Occlusion W Cer Inf        |                        |             |     |                  | TEDN   | 114    |
| 223         | -16             | 06/07/2012                     |                | Px        | 70553 | Inpt | Radio              | 1     | Mri Brain Brain Stem W/O &w/Contrast Mate |                        |             |     |                  | TEDN   | 114    |
| 224         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 118    |
| 225         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43820 |      |                    | 2     | Hemiplegia Uns Side Cv Disease            |                        |             |     |                  | TEDI   | 118    |
| 226         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43882 |      |                    | 3     | Dysphagia Cerebrovascular Disease         |                        |             |     |                  | TEDI   | 118    |
| 227         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 43889 |      |                    | 4     | Oth Late Effects Cv Disease               |                        |             |     |                  | TEDI   | 118    |
| 228         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7812  |      |                    | 5     | Abnormality Of Gait                       |                        |             |     |                  | TEDI   | 118    |
| 229         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 42731 |      |                    | 6     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 118    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|------|--------------------|-------|-------------------------------------------|-------------------------|-------------|-----|------------------|--------|--------|
| 230         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 29420            |      |                    | 7     | Dementia Unspec Wo Behav Disturb          |                         |             |     |                  | TEDI   | 118    |
| 231         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7202             |      |                    | 8     | Sacroiliitis Other                        |                         |             |     |                  | TEDI   | 118    |
| 232         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | 7102             |      |                    | 9     | Sicca Syndrome                            |                         |             |     |                  | TEDI   | 118    |
| 233         | -15             | 06/08/2012                     | 06/23/2012     | Dx        | V5861            |      |                    | 10    | Encounter Long Term Anticoagulant         |                         |             |     |                  | TEDI   | 118    |
| 234         | -15             | 06/08/2012                     |                | Dx        | 42731            | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 115    |
| 235         | -15             | 06/08/2012                     |                | Dx        | 4011             | Inpt | Cardvasc           | 2     | Benign Essential Hypertension             |                         |             |     |                  | TEDN   | 115    |
| 236         | -15             | 06/08/2012                     |                | Dx        | 2720             | Inpt | Cardvasc           | 3     | Pure Hypercholesterolemia                 |                         |             |     |                  | TEDN   | 115    |
| 237         | -15             | 06/08/2012                     |                | Dx        | 5789             | Inpt | Cardvasc           | 4     | Uns Hemorr Gastrointestinal Tract         |                         |             |     |                  | TEDN   | 115    |
| 238         | -15             | 06/08/2012                     |                | Px        | 99231            | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                         |             |     |                  | TEDN   | 115    |
| 239         | -15             | 06/08/2012                     |                | Dx        | 42731            | Inpt | Intmed             | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 116    |
| 240         | -15             | 06/08/2012                     |                | Dx        | 436              | Inpt | Intmed             | 2     | Acute Ill Defined Cv Disease              |                         |             |     |                  | TEDN   | 116    |
| 241         | -15             | 06/08/2012                     |                | Dx        | V5861            | Inpt | Intmed             | 3     | Encounter Long Term Anticoagulant         |                         |             |     |                  | TEDN   | 116    |
| 242         | -15             | 06/08/2012                     |                | Px        | 99238            | Inpt | Intmed             | 1     | Hospital Discharge Day Management 30 Min/ |                         |             |     |                  | TEDN   | 116    |
| 243         | -15             | 06/08/2012                     |                | Dx        | 725              | Inpt | Grpprac            | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 117    |
| 244         | -15             | 06/08/2012                     |                | Dx        | 7102             | Inpt | Grpprac            | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 117    |
| 245         | -15             | 06/08/2012                     |                | Px        | 99222            | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                         |             |     |                  | TEDN   | 117    |
| 246         | -12             | 06/11/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 119    |
| 247         | -12             | 06/11/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 119    |
| 248         | -12             | 06/11/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 119    |
| 249         | -11             | 06/12/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 120    |
| 250         | -11             | 06/12/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 120    |
| 251         | -11             | 06/12/2012                     |                | Px        | 99231            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 15 Minutes         |                         |             |     |                  | TEDN   | 120    |
| 252         | -10             | 06/13/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 121    |
| 253         | -10             | 06/13/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 121    |
| 254         | -10             | 06/13/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 121    |
| 255         | -8              | 06/15/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 122    |
| 256         | -8              | 06/15/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 122    |
| 257         | -8              | 06/15/2012                     |                | Px        | 99232            | Inpt | Physi              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                  | TEDN   | 122    |
| 258         | -1              | 06/22/2012                     |                | Dx        | 725              | Inpt | Physi              | 1     | Polymyalgia Rheumatica                    |                         |             |     |                  | TEDN   | 123    |
| 259         | -1              | 06/22/2012                     |                | Dx        | 7102             | Inpt | Physi              | 2     | Sicca Syndrome                            |                         |             |     |                  | TEDN   | 123    |
| 260         | -1              | 06/22/2012                     |                | Px        | 99238            | Inpt | Physi              | 1     | Hospital Discharge Day Management 30 Min/ |                         |             |     |                  | TEDN   | 123    |
| 261         | 0               | 06/23/2012                     |                | Dx        | 79902            |      | Medic              | 1     | Hypoxemia                                 |                         |             |     |                  | TEDN   | 127    |
| 262         | 0               | 06/23/2012                     |                | Px        | E0431            |      | Medic              | 1     | Portable Gaseous O2                       |                         |             |     |                  | TEDN   | 127    |
| 263         | 0               | 06/23/2012                     |                | Px        | E1390            |      | Medic              | 1     | Oxygen Concentrator                       |                         |             |     |                  | TEDN   | 128    |
| 264         | 0               | 06/23/2012                     |                | Rx        | 00406051201      |      |                    |       |                                           | Oxycodone-Acetaminophen | 5           | 30  | Tablet           | PDTS   | 124    |
| 265         | 0               | 06/23/2012                     |                | Rx        | 51672402703      |      |                    |       |                                           | Warfarin Sodium         | 30          | 30  | Tablet           | PDTS   | 125    |
| 266         | 0               | 06/23/2012                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |       |                                           | INDEX STUDY DRUG        | 30          |     | INITIAL FILL     | PDTS   | 126    |
| 267         | 2               | 06/25/2012                     |                | Dx        | 42731            |      | Intmed             | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 129    |
| 268         | 2               | 06/25/2012                     |                | Px        | 85610            |      | Intmed             | 1     | Prothrombin Time                          |                         |             |     |                  | TEDN   | 129    |
| 269         | 2               | 06/25/2012                     |                | Px        | 99213            |      | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                         |             |     |                  | TEDN   | 130    |
| 270         | 4               | 06/27/2012                     |                | Dx        | 42731            |      | Cardvasc           | 1     | Atrial Fibrillation                       |                         |             |     |                  | TEDN   | 133    |
| 271         | 4               | 06/27/2012                     |                | Dx        | 4011             |      | Cardvasc           | 2     | Benign Essential Hypertension             |                         |             |     |                  | TEDN   | 133    |
| 272         | 4               | 06/27/2012                     |                | Dx        | 4242             |      | Cardvasc           | 3     | Tricuspid Valve Disorders Nonrheum        |                         |             |     |                  | TEDN   | 133    |
| 273         | 4               | 06/27/2012                     |                | Dx        | 4240             |      | Cardvasc           | 4     | Mitral Valve Disorders                    |                         |             |     |                  | TEDN   | 133    |
| 274         | 4               | 06/27/2012                     |                | Px        | 99215            |      | Cardvasc           | 1     | Office Outpatient Visit 40 Minutes        |                         |             |     |                  | TEDN   | 133    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 275         | 4               | 06/27/2012                     |                | Rx        | 68180051403      |     |                    |       |                                           | Lisinopril                  | 30          | 30  | Tablet                       | PDTS   | 131    |
| 276         | 4               | 06/27/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide         | 30          | 30  | Tablet                       | PDTS   | 132    |
| 277         | 6               | 06/29/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 134    |
| 278         | 6               | 06/29/2012                     |                | Px        | 92960            |     | Cardvasc           | 1     | Cardioversion Elective Arrhythmia Externa |                             |             |     |                              | TEDN   | 134    |
| 279         | 9               | 07/02/2012                     |                | Dx        | 7102             |     | Intmed             | 1     | Sicca Syndrome                            |                             |             |     |                              | TEDN   | 135    |
| 280         | 9               | 07/02/2012                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 135    |
| 281         | 9               | 07/02/2012                     |                | Dx        | 7812             |     | Intmed             | 3     | Abnormality Of Gait                       |                             |             |     |                              | TEDN   | 135    |
| 282         | 9               | 07/02/2012                     |                | Px        | G0180            |     | Intmed             | 1     | Md Certification Hha Patient              |                             |             |     |                              | TEDN   | 135    |
| 283         | 10              | 07/03/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 136    |
| 284         | 10              | 07/03/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 136    |
| 285         | 10              | 07/03/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 137    |
| 286         | 16              | 07/09/2012                     |                | Rx        | 53746027205      |     |                    |       |                                           | Sulfamethoxazole-Trimethopr | 7           | 14  | Tablet                       | PDTS   | 138    |
| 287         | 17              | 07/10/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 140    |
| 288         | 17              | 07/10/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 140    |
| 289         | 17              | 07/10/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 141    |
| 290         | 17              | 07/10/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 139    |
| 291         | 20              | 07/13/2012                     |                | Dx        | 7245             |     | Facility           | 1     | Backache Unspecified                      |                             |             |     |                              | TEDN   | 144    |
| 292         | 20              | 07/13/2012                     |                | Px        | 72110            |     | Facility           | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                             |             |     |                              | TEDN   | 144    |
| 293         | 20              | 07/13/2012                     |                | Dx        | 7213             |     | Radio              | 1     | Lumbosacral Spondylosis                   |                             |             |     |                              | TEDN   | 143    |
| 294         | 20              | 07/13/2012                     |                | Px        | 72110            |     | Radio              | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                             |             |     |                              | TEDN   | 143    |
| 295         | 20              | 07/13/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       | INDEX STUDY DRUG                          |                             | 30          |     | REFILL                       | PDTS   | 142    |
| 296         | 24              | 07/17/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 146    |
| 297         | 24              | 07/17/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 146    |
| 298         | 24              | 07/17/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 147    |
| 299         | 24              | 07/17/2012                     |                | Rx        | 51672402703      |     |                    |       |                                           | Warfarin Sodium             | 90          | 180 | Tablet                       | PDTS   | 145    |
| 300         | 27              | 07/20/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide         | 30          | 30  | Tablet                       | PDTS   | 148    |
| 301         | 30              | 07/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                             |             |     |                              | TEDN   | 149    |
| 302         | 30              | 07/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                             |             |     |                              | TEDN   | 149    |
| 303         | 30              | 07/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 150    |
| 304         | 31              | 07/24/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 151    |
| 305         | 31              | 07/24/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 151    |
| 306         | 31              | 07/24/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 152    |
| 307         | 34              | 07/27/2012                     |                | Dx        | 7241             |     | Intmed             | 1     | Pain In Thoracic Spine                    |                             |             |     |                              | TEDN   | 155    |
| 308         | 34              | 07/27/2012                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 155    |
| 309         | 34              | 07/27/2012                     |                | Dx        | 7881             |     | Intmed             | 3     | Dysuria                                   |                             |             |     |                              | TEDN   | 155    |
| 310         | 34              | 07/27/2012                     |                | Px        | 81002            |     | Intmed             | 1     | Urnl Dip Stick/Tablet Rgnt Non-Auto W/O   |                             |             |     |                              | TEDN   | 155    |
| 311         | 34              | 07/27/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 156    |
| 312         | 34              | 07/27/2012                     |                | Rx        | 63481068706      |     |                    |       |                                           | Lidoderm                    | 30          | 30  | Adhesive Patch, Medicated    | PDTS   | 153    |
| 313         | 34              | 07/27/2012                     |                | Rx        | 00406051201      |     |                    |       |                                           | Oxycodone-Acetaminophen     | 33          | 50  | Tablet                       | PDTS   | 154    |
| 314         | 38              | 07/31/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 157    |
| 315         | 38              | 07/31/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 157    |
| 316         | 38              | 07/31/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 158    |
| 317         | 38              | 07/31/2012                     |                | Dx        | 72142            |     | Facility           | 1     | Spondylosis W Myelopathy Lumbar           |                             |             |     |                              | TEDN   | 159    |
| 318         | 38              | 07/31/2012                     |                | Dx        | 73730            |     | Facility           | 2     | Scoliosis Idiopathic                      |                             |             |     |                              | TEDN   | 159    |
| 319         | 38              | 07/31/2012                     |                | Dx        | 72402            |     | Facility           | 3     | Spinal Stenos Lumbar Wo Neur Claud        |                             |             |     |                              | TEDN   | 159    |
| 320         | 38              | 07/31/2012                     |                | Px        | 72158            |     | Facility           | 1     | Mri Spinal Canal Lumbar W/O &w/Contr Matr |                             |             |     |                              | TEDN   | 159    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 321         | 38              | 07/31/2012                     |                | Dx        | 8054             |     | Radio              | 1     | Fracture Lumbar Vertebra Close            |                        |             |     |                              | TEDN   | 160    |
| 322         | 38              | 07/31/2012                     |                | Dx        | E887             |     | Radio              | 2     | Fracture In Accidental Fall Uns           |                        |             |     |                              | TEDN   | 160    |
| 323         | 38              | 07/31/2012                     |                | Px        | 72158            |     | Radio              | 1     | Mri Spinal Canal Lumbar W/O &w/Contr Matr |                        |             |     |                              | TEDN   | 160    |
| 324         | 45              | 08/07/2012                     |                | Dx        | 37515            |     | Opth               | 1     | Uns Tear Film Insufficiency               |                        |             |     |                              | TEDN   | 161    |
| 325         | 45              | 08/07/2012                     |                | Dx        | 36501            |     | Opth               | 2     | Op Angle Borderline Low Risk              |                        |             |     |                              | TEDN   | 161    |
| 326         | 45              | 08/07/2012                     |                | Dx        | 36257            |     | Opth               | 3     | Drusen (Degenerative) Of Retina           |                        |             |     |                              | TEDN   | 161    |
| 327         | 45              | 08/07/2012                     |                | Px        | 92012            |     | Opth               | 1     | Opth Medical Xm&eval Intermediate Estab   |                        |             |     |                              | TEDN   | 161    |
| 328         | 45              | 08/07/2012                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 162    |
| 329         | 45              | 08/07/2012                     |                | Dx        | 2449             |     | Grppract           | 2     | Uns Hypothyroidism                        |                        |             |     |                              | TEDN   | 162    |
| 330         | 45              | 08/07/2012                     |                | Dx        | 538              |     | Grppract           | 3     | Gastrointestinal Mucositis                |                        |             |     |                              | TEDN   | 162    |
| 331         | 45              | 08/07/2012                     |                | Dx        | 4240             |     | Grppract           | 4     | Mitral Valve Disorders                    |                        |             |     |                              | TEDN   | 162    |
| 332         | 45              | 08/07/2012                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 162    |
| 333         | 49              | 08/11/2012                     |                | Rx        | 00603385632      |     |                    |       |                                           | Hydrochlorothiazide    | 90          | 90  | Tablet                       | PDTS   | 163    |
| 334         | 49              | 08/11/2012                     |                | Rx        | 68180051403      |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                       | PDTS   | 164    |
| 335         | 49              | 08/11/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 165    |
| 336         | 49              | 08/11/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 166    |
| 337         | 51              | 08/13/2012                     |                | Rx        | 00054001725      |     |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                       | PDTS   | 167    |
| 338         | 52              | 08/14/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 168    |
| 339         | 52              | 08/14/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 168    |
| 340         | 52              | 08/14/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 169    |
| 341         | 61              | 08/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 170    |
| 342         | 61              | 08/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 170    |
| 343         | 61              | 08/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 171    |
| 344         | 62              | 08/24/2012                     |                | Dx        | 73313            |     | Intmed             | 1     | Pathological Fracture Vertebrae           |                        |             |     |                              | TEDN   | 172    |
| 345         | 62              | 08/24/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 172    |
| 346         | 69              | 08/31/2012                     |                | Dx        | 42731            |     | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 173    |
| 347         | 69              | 08/31/2012                     |                | Dx        | 7242             |     | Intmed             | 2     | Lumbago                                   |                        |             |     |                              | TEDN   | 173    |
| 348         | 69              | 08/31/2012                     |                | Px        | G0179            |     | Intmed             | 1     | Md Recertification Hha Pt                 |                        |             |     |                              | TEDN   | 173    |
| 349         | 69              | 08/31/2012                     |                | Dx        | 8054             |     | Radio              | 1     | Fracture Lumbar Vertebra Close            |                        |             |     |                              | TEDN   | 174    |
| 350         | 69              | 08/31/2012                     |                | Px        | 22521            |     | Radio              | 1     | Percutaneous Vertebroplasty Lumbar W/Wo B |                        |             |     |                              | TEDN   | 174    |
| 351         | 69              | 08/31/2012                     |                | Px        | 72291            |     | Radio              | 1     | Rad S&i Perq Vrtpls/Sacrplsty Pr Vrt Body |                        |             |     |                              | TEDN   | 175    |
| 352         | 69              | 08/31/2012                     |                | Px        | 85027            |     | Grppract           | 1     | Blood Count Complete Automated            |                        |             |     |                              | TEDN   | 176    |
| 353         | 69              | 08/31/2012                     |                | Px        | 85610            |     | Grppract           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 177    |
| 354         | 69              | 08/31/2012                     |                | Px        | 85730            |     | Grppract           | 1     | Thromboplastin Time Partial Plasma/Whole  |                        |             |     |                              | TEDN   | 178    |
| 355         | 73              | 09/04/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 179    |
| 356         | 73              | 09/04/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 179    |
| 357         | 73              | 09/04/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 180    |
| 358         | 77              | 09/08/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 181    |
| 359         | 79              | 09/10/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                       | PDTS   | 182    |
| 360         | 87              | 09/18/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                              | TEDN   | 183    |
| 361         | 87              | 09/18/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 183    |
| 362         | 87              | 09/18/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 184    |
| 363         | 92              | 09/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                              | TEDN   | 185    |
| 364         | 92              | 09/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                              | TEDN   | 185    |
| 365         | 92              | 09/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 186    |
| 366         | 93              | 09/24/2012                     |                | Dx        | 7213             |     | Radio              | 1     | Lumbosacral Spondylosis                   |                        |             |     |                              | TEDN   | 188    |



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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 367         | 93              | 09/24/2012                     |                | Px        | 72110            |     | Radio              | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                        |             |     |                               | TEDN   | 188    |
| 368         | 93              | 09/24/2012                     |                | Dx        | 7241             |     | Intmed             | 1     | Pain In Thoracic Spine                    |                        |             |     |                               | TEDN   | 189    |
| 369         | 93              | 09/24/2012                     |                | Dx        | 73313            |     | Intmed             | 2     | Pathological Fracture Vertebrae           |                        |             |     |                               | TEDN   | 189    |
| 370         | 93              | 09/24/2012                     |                | Dx        | V0481            |     | Intmed             | 3     | Vaccine For Influenza                     |                        |             |     |                               | TEDN   | 189    |
| 371         | 93              | 09/24/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 189    |
| 372         | 93              | 09/24/2012                     |                | Px        | G0008            |     | Intmed             | 1     | Admin Influenza Virus Vac                 |                        |             |     |                               | TEDN   | 190    |
| 373         | 93              | 09/24/2012                     |                | Px        | Q2037            |     | Intmed             | 1     | Fluvirin Vacc, 3 Yrs & >, Im              |                        |             |     |                               | TEDN   | 191    |
| 374         | 93              | 09/24/2012                     |                | Dx        | 73300            |     | Facility           | 1     | Osteoporosis Unspec                       |                        |             |     |                               | TEDN   | 192    |
| 375         | 93              | 09/24/2012                     |                | Dx        | 7212             |     | Facility           | 2     | Thoracic Spondylosis Wo Myelopathy        |                        |             |     |                               | TEDN   | 192    |
| 376         | 93              | 09/24/2012                     |                | Dx        | 7213             |     | Facility           | 3     | Lumbosacral Spondylosis                   |                        |             |     |                               | TEDN   | 192    |
| 377         | 93              | 09/24/2012                     |                | Dx        | V4589            |     | Facility           | 4     | Oth Postsurgical Status                   |                        |             |     |                               | TEDN   | 192    |
| 378         | 93              | 09/24/2012                     |                | Px        | 72110            |     | Facility           | 1     | Radex Spine Lumbosacral Minimum 4 Views   |                        |             |     |                               | TEDN   | 192    |
| 379         | 93              | 09/24/2012                     |                | Rx        | 00603307932      |     |                    |       |                                           | Cyclobenzaprine Hcl    | 15          | 15  | Tablet                        | PDTS   | 187    |
| 380         | 101             | 10/02/2012                     |                | Dx        | 42731            |     | Intmed             | 1     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 194    |
| 381         | 101             | 10/02/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 194    |
| 382         | 101             | 10/02/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 195    |
| 383         | 101             | 10/02/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 193    |
| 384         | 109             | 10/10/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 196    |
| 385         | 115             | 10/16/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 197    |
| 386         | 115             | 10/16/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 197    |
| 387         | 115             | 10/16/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 198    |
| 388         | 122             | 10/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 199    |
| 389         | 122             | 10/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 199    |
| 390         | 122             | 10/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 200    |
| 391         | 131             | 11/01/2012                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 201    |
| 392         | 131             | 11/01/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 201    |
| 393         | 131             | 11/01/2012                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 202    |
| 394         | 134             | 11/04/2012                     |                | Rx        | 51672402703      |     |                    |       |                                           | Warfarin Sodium        | 90          | 180 | Tablet                        | PDTS   | 203    |
| 395         | 134             | 11/04/2012                     |                | Rx        | 55111015810      |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 204    |
| 396         | 135             | 11/05/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                        | PDTS   | 205    |
| 397         | 141             | 11/11/2012                     |                | Rx        | 00054001729      |     |                    |       |                                           | Prednisone             | 90          | 90  | Tablet                        | PDTS   | 206    |
| 398         | 141             | 11/11/2012                     |                | Rx        | 68645028254      |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 207    |
| 399         | 143             | 11/13/2012                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 209    |
| 400         | 143             | 11/13/2012                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension             |                        |             |     |                               | TEDN   | 209    |
| 401         | 143             | 11/13/2012                     |                | Px        | 93040            |     | Grppract           | 1     | Rhythm Ecg 1-3 Leads W/Interpretation & R |                        |             |     |                               | TEDN   | 209    |
| 402         | 143             | 11/13/2012                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 210    |
| 403         | 143             | 11/13/2012                     |                | Rx        | 63304062410      |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 208    |
| 404         | 145             | 11/15/2012                     |                | Rx        | 00245005815      |     |                    |       |                                           | Klor-Con M20           | 12          | 38  | Tablet, SR,particles/Crystals | PDTS   | 211    |
| 405         | 153             | 11/23/2012                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 212    |
| 406         | 153             | 11/23/2012                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 212    |
| 407         | 153             | 11/23/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 213    |
| 408         | 157             | 11/27/2012                     |                | Dx        | 4280             |     | Intmed             | 1     | Congestive Heart Failure Unspec           |                        |             |     |                               | TEDN   | 214    |
| 409         | 157             | 11/27/2012                     |                | Dx        | 45111            |     | Intmed             | 2     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 214    |
| 410         | 157             | 11/27/2012                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 214    |
| 411         | 157             | 11/27/2012                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 215    |
| 412         | 172             | 12/12/2012                     |                | Rx        | 63304062410      |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 216    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 413         | 172             | 12/12/2012                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 217    |
| 414         | 172             | 12/12/2012                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 12          | 38  | Tablet, SR,particles/Crystals | PDTS   | 218    |
| 415         | 178             | 12/18/2012                     |                | Dx        | 4280        |     | Intmed             | 1     | Congestive Heart Failure Unspec           |                        |             |     |                               | TEDN   | 220    |
| 416         | 178             | 12/18/2012                     |                | Dx        | 42731       |     | Intmed             | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 220    |
| 417         | 178             | 12/18/2012                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 220    |
| 418         | 178             | 12/18/2012                     |                | Px        | 99213       |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                               | TEDN   | 221    |
| 419         | 178             | 12/18/2012                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 219    |
| 420         | 183             | 12/23/2012                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 222    |
| 421         | 183             | 12/23/2012                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 222    |
| 422         | 183             | 12/23/2012                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 223    |
| 423         | 198             | 01/07/2013                     |                | Dx        | 7847        |     | Gp                 | 1     | Epistaxis                                 |                        |             |     |                               | TEDN   | 224    |
| 424         | 198             | 01/07/2013                     |                | Dx        | 59970       |     | Gp                 | 2     | Hematuria Unspecified                     |                        |             |     |                               | TEDN   | 224    |
| 425         | 198             | 01/07/2013                     |                | Dx        | 42731       |     | Gp                 | 3     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 224    |
| 426         | 198             | 01/07/2013                     |                | Dx        | 4019        |     | Gp                 | 4     | Unspecified Essential Hypertension        |                        |             |     |                               | TEDN   | 224    |
| 427         | 198             | 01/07/2013                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                        |             |     |                               | TEDN   | 224    |
| 428         | 198             | 01/07/2013                     |                | Dx        | 7847        |     | Facility           | 1     | Epistaxis                                 |                        |             |     |                               | TEDN   | 225    |
| 429         | 198             | 01/07/2013                     |                | Dx        | 59971       |     | Facility           | 2     | Gross Hematuria                           |                        |             |     |                               | TEDN   | 225    |
| 430         | 198             | 01/07/2013                     |                | Px        | 80048       |     | Facility           | 1     | Basic Metabolic Panel Calcium Total       |                        |             |     |                               | TEDN   | 225    |
| 431         | 198             | 01/07/2013                     |                | Px        | 81001       |     | Facility           | 1     | Urns Dip Stick/Tablet Reagent Auto Micro  |                        |             |     |                               | TEDN   | 226    |
| 432         | 198             | 01/07/2013                     |                | Px        | 85027       |     | Facility           | 1     | Blood Count Complete Automated            |                        |             |     |                               | TEDN   | 227    |
| 433         | 198             | 01/07/2013                     |                | Px        | 85610       |     | Facility           | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 228    |
| 434         | 198             | 01/07/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                               | TEDN   | 229    |
| 435         | 201             | 01/10/2013                     |                | Dx        | 7030        |     | Podia              | 1     | Ingrowing Nail                            |                        |             |     |                               | TEDN   | 230    |
| 436         | 201             | 01/10/2013                     |                | Dx        | 7038        |     | Podia              | 2     | Other Diseases Nail                       |                        |             |     |                               | TEDN   | 230    |
| 437         | 201             | 01/10/2013                     |                | Dx        | 700         |     | Podia              | 3     | Corns/Callosities                         |                        |             |     |                               | TEDN   | 230    |
| 438         | 201             | 01/10/2013                     |                | Dx        | 44020       |     | Podia              | 4     | Uns Atherosclerosis Extremities           |                        |             |     |                               | TEDN   | 230    |
| 439         | 201             | 01/10/2013                     |                | Px        | 11055       |     | Podia              | 1     | Paring/Cutting Benign Hyperkeratotic Lesi |                        |             |     |                               | TEDN   | 230    |
| 440         | 201             | 01/10/2013                     |                | Px        | 11721       |     | Podia              | 1     | Debridement Nail Any Method 6/>           |                        |             |     |                               | TEDN   | 231    |
| 441         | 201             | 01/10/2013                     |                | Px        | 11730       |     | Podia              | 1     | Avulsion Nail Plate Partial/Complete Simp |                        |             |     |                               | TEDN   | 232    |
| 442         | 201             | 01/10/2013                     |                | Px        | 99203       |     | Podia              | 1     | Office Outpatient New 30 Minutes          |                        |             |     |                               | TEDN   | 233    |
| 443         | 206             | 01/15/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 235    |
| 444         | 206             | 01/15/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 235    |
| 445         | 206             | 01/15/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 236    |
| 446         | 206             | 01/15/2013                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 234    |
| 447         | 207             | 01/16/2013                     |                | Rx        | 63304062410 |     |                    |       |                                           | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 237    |
| 448         | 209             | 01/18/2013                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 238    |
| 449         | 213             | 01/22/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 239    |
| 450         | 213             | 01/22/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 239    |
| 451         | 213             | 01/22/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                               | TEDN   | 240    |
| 452         | 214             | 01/23/2013                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 241    |
| 453         | 214             | 01/23/2013                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 241    |
| 454         | 214             | 01/23/2013                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 242    |
| 455         | 215             | 01/24/2013                     |                | Rx        | 68180051403 |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 243    |
| 456         | 215             | 01/24/2013                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 38          | 38  | Tablet, SR,particles/Crystals | PDTS   | 244    |
| 457         | 220             | 01/29/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                        |             |     |                               | TEDN   | 245    |
| 458         | 220             | 01/29/2013                     |                | Px        | 85610       |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                               | TEDN   | 245    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 459         | 220             | 01/29/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 246    |
| 460         | 227             | 02/05/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 247    |
| 461         | 227             | 02/05/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 247    |
| 462         | 227             | 02/05/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 248    |
| 463         | 232             | 02/10/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 249    |
| 464         | 232             | 02/10/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG       | 90          |     | REFILL                        | PDTS   | 250    |
| 465         | 232             | 02/10/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 251    |
| 466         | 233             | 02/11/2013                     |                | Rx        | 00054001729      |     |                    |       |                                      | Prednisone             | 90          | 90  | Tablet                        | PDTS   | 252    |
| 467         | 241             | 02/19/2013                     |                | Dx        | 42731            |     | Grppract           | 1     | Atrial Fibrillation                  |                        |             |     |                               | TEDN   | 254    |
| 468         | 241             | 02/19/2013                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension        |                        |             |     |                               | TEDN   | 254    |
| 469         | 241             | 02/19/2013                     |                | Dx        | 4240             |     | Grppract           | 3     | Mitral Valve Disorders               |                        |             |     |                               | TEDN   | 254    |
| 470         | 241             | 02/19/2013                     |                | Dx        | 4242             |     | Grppract           | 4     | Tricuspid Valve Disorders Nonrheum   |                        |             |     |                               | TEDN   | 254    |
| 471         | 241             | 02/19/2013                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes   |                        |             |     |                               | TEDN   | 254    |
| 472         | 241             | 02/19/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 255    |
| 473         | 241             | 02/19/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 255    |
| 474         | 241             | 02/19/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 256    |
| 475         | 241             | 02/19/2013                     |                | Rx        | 62037099905      |     |                    |       |                                      | Potassium Chloride     | 90          | 90  | Tablet, SR,particles/Crystals | PDTS   | 253    |
| 476         | 245             | 02/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 257    |
| 477         | 245             | 02/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 257    |
| 478         | 245             | 02/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                        |             |     |                               | TEDN   | 258    |
| 479         | 248             | 02/26/2013                     |                | Rx        | 68645028254      |     |                    |       |                                      | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 259    |
| 480         | 253             | 03/03/2013                     |                | Rx        | 51672402703      |     |                    |       |                                      | Warfarin Sodium        | 90          | 180 | Tablet                        | PDTS   | 260    |
| 481         | 258             | 03/08/2013                     |                | Rx        | 53489021510      |     |                    |       |                                      | Clonidine Hcl          | 30          | 30  | Tablet                        | PDTS   | 261    |
| 482         | 262             | 03/12/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 262    |
| 483         | 262             | 03/12/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 262    |
| 484         | 262             | 03/12/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes    |                        |             |     |                               | TEDN   | 263    |
| 485         | 266             | 03/16/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 264    |
| 486         | 266             | 03/16/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 265    |
| 487         | 269             | 03/19/2013                     |                | Dx        | 4280             |     | Intmed             | 1     | Congestive Heart Failure Unspec      |                        |             |     |                               | TEDN   | 266    |
| 488         | 269             | 03/19/2013                     |                | Dx        | 4011             |     | Intmed             | 2     | Benign Essential Hypertension        |                        |             |     |                               | TEDN   | 266    |
| 489         | 269             | 03/19/2013                     |                | Px        | 99214            |     | Intmed             | 1     | Office Outpatient Visit 25 Minutes   |                        |             |     |                               | TEDN   | 266    |
| 490         | 273             | 03/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 267    |
| 491         | 273             | 03/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 267    |
| 492         | 273             | 03/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                        |             |     |                               | TEDN   | 268    |
| 493         | 281             | 03/31/2013                     |                | Rx        | 68645028254      |     |                    |       |                                      | Citalopram Hbr         | 30          | 30  | Tablet                        | PDTS   | 269    |
| 494         | 281             | 03/31/2013                     |                | Rx        | 53489021510      |     |                    |       |                                      | Clonidine Hcl          | 30          | 30  | Tablet                        | PDTS   | 270    |
| 495         | 284             | 04/03/2013                     |                | Rx        | 68180051403      |     |                    |       |                                      | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 271    |
| 496         | 290             | 04/09/2013                     |                | Rx        | 55111015810      |     |                    |       |                                      | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)  | PDTS   | 272    |
| 497         | 290             | 04/09/2013                     |                | Rx        | 63304062410      |     |                    |       |                                      | Furosemide             | 30          | 30  | Tablet                        | PDTS   | 273    |
| 498         | 293             | 04/12/2013                     |                | Dx        | 6826             |     | Intmed             | 1     | Cellulitis/Abscess Leg Ex Foot       |                        |             |     |                               | TEDN   | 275    |
| 499         | 293             | 04/12/2013                     |                | Dx        | 45111            |     | Intmed             | 2     | Phlebitis Femoral Vein               |                        |             |     |                               | TEDN   | 275    |
| 500         | 293             | 04/12/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                     |                        |             |     |                               | TEDN   | 275    |
| 501         | 293             | 04/12/2013                     |                | Px        | 99213            |     | Intmed             | 1     | Office Outpatient Visit 15 Minutes   |                        |             |     |                               | TEDN   | 276    |
| 502         | 293             | 04/12/2013                     |                | Rx        | 68180012202      |     |                    |       |                                      | Cephalexin             | 7           | 21  | Capsule (Hard, Soft, Etc.)    | PDTS   | 274    |
| 503         | 304             | 04/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                            |                        |             |     |                               | TEDN   | 277    |
| 504         | 304             | 04/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                  |                        |             |     |                               | TEDN   | 277    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------------|------------------------|-------------|-----|--------------------------------|--------|--------|
| 505         | 304             | 04/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                                | TEDN   | 278    |
| 506         | 312             | 05/01/2013                     |                | Rx        | 00054001729      |     |                    |       |                                            | Prednisone             | 90          | 90  | Tablet                         | PDTS   | 279    |
| 507         | 312             | 05/01/2013                     |                | Rx        | 53489021510      |     |                    |       |                                            | Clonidine Hcl          | 30          | 30  | Tablet                         | PDTS   | 280    |
| 508         | 312             | 05/01/2013                     |                | Rx        | 68645028254      |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                         | PDTS   | 281    |
| 509         | 318             | 05/07/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                                | TEDN   | 282    |
| 510         | 318             | 05/07/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                                | TEDN   | 282    |
| 511         | 318             | 05/07/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 282    |
| 512         | 318             | 05/07/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                                | TEDN   | 283    |
| 513         | 323             | 05/12/2013                     |                | Rx        | 63304062410      |     |                    |       |                                            | Furosemide             | 30          | 30  | Tablet                         | PDTS   | 284    |
| 514         | 323             | 05/12/2013                     |                | Rx        | 55111015810      |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)   | PDTS   | 285    |
| 515         | 323             | 05/12/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                            | INDEX STUDY DRUG       | 90          |     | REFILL                         | PDTS   | 286    |
| 516         | 334             | 05/23/2013                     |                | Dx        | 79902            |     | Medic              | 1     | Hypoxemia                                  |                        |             |     |                                | TEDN   | 287    |
| 517         | 334             | 05/23/2013                     |                | Px        | E0431            |     | Medic              | 1     | Portable Gaseous O2                        |                        |             |     |                                | TEDN   | 287    |
| 518         | 334             | 05/23/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                        |                        |             |     |                                | TEDN   | 288    |
| 519         | 346             | 06/04/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                                | TEDN   | 291    |
| 520         | 346             | 06/04/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                                | TEDN   | 291    |
| 521         | 346             | 06/04/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 291    |
| 522         | 346             | 06/04/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                                | TEDN   | 292    |
| 523         | 346             | 06/04/2013                     |                | Rx        | 68645028254      |     |                    |       |                                            | Citalopram Hbr         | 30          | 30  | Tablet                         | PDTS   | 289    |
| 524         | 346             | 06/04/2013                     |                | Rx        | 53489021510      |     |                    |       |                                            | Clonidine Hcl          | 30          | 30  | Tablet                         | PDTS   | 290    |
| 525         | 348             | 06/06/2013                     |                | Rx        | 00245005815      |     |                    |       |                                            | Klor-Con M20           | 90          | 90  | Tablet, SR, particles/Crystals | PDTS   | 293    |
| 526         | 352             | 06/10/2013                     |                | Rx        | 68180051403      |     |                    |       |                                            | Lisinopril             | 30          | 60  | Tablet                         | PDTS   | 294    |
| 527         | 353             | 06/11/2013                     |                | Rx        | 55111015810      |     |                    |       |                                            | Omeprazole             | 30          | 30  | Capsule, DR (Enteric Coated)   | PDTS   | 295    |
| 528         | 353             | 06/11/2013                     |                | Rx        | 63304062410      |     |                    |       |                                            | Furosemide             | 30          | 30  | Tablet                         | PDTS   | 296    |
| 529         | 356             | 06/14/2013                     |                | Dx        | 78903            |     | Gp                 | 1     | Abdom Pain R Lower Quad                    |                        |             |     |                                | TEDN   | 298    |
| 530         | 356             | 06/14/2013                     |                | Dx        | 56400            |     | Gp                 | 2     | Unspec Constipation                        |                        |             |     |                                | TEDN   | 298    |
| 531         | 356             | 06/14/2013                     |                | Dx        | 5990             |     | Gp                 | 3     | Urinary Tract Infection Unspec             |                        |             |     |                                | TEDN   | 298    |
| 532         | 356             | 06/14/2013                     |                | Dx        | 56032            |     | Gp                 | 4     | Fecal Impaction                            |                        |             |     |                                | TEDN   | 298    |
| 533         | 356             | 06/14/2013                     |                | Px        | 99285            |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                                | TEDN   | 298    |
| 534         | 356             | 06/14/2013                     |                | Dx        | 78909            |     | Facility           | 1     | Abdominal Pain Other Site                  |                        |             |     |                                | TEDN   | 299    |
| 535         | 356             | 06/14/2013                     |                | Dx        | 56400            |     | Facility           | 2     | Unspec Constipation                        |                        |             |     |                                | TEDN   | 299    |
| 536         | 356             | 06/14/2013                     |                | Dx        | 56032            |     | Facility           | 3     | Fecal Impaction                            |                        |             |     |                                | TEDN   | 299    |
| 537         | 356             | 06/14/2013                     |                | Dx        | 5990             |     | Facility           | 4     | Urinary Tract Infection Unspec             |                        |             |     |                                | TEDN   | 299    |
| 538         | 356             | 06/14/2013                     |                | Dx        | 55320            |     | Facility           | 5     | Ventral Hernia Unspec                      |                        |             |     |                                | TEDN   | 299    |
| 539         | 356             | 06/14/2013                     |                | Dx        | 5533             |     | Facility           | 6     | Diaphragmatic Hernia                       |                        |             |     |                                | TEDN   | 299    |
| 540         | 356             | 06/14/2013                     |                | Dx        | 4019             |     | Facility           | 7     | Unspecified Essential Hypertension         |                        |             |     |                                | TEDN   | 299    |
| 541         | 356             | 06/14/2013                     |                | Dx        | 2449             |     | Facility           | 8     | Uns Hypothyroidism                         |                        |             |     |                                | TEDN   | 299    |
| 542         | 356             | 06/14/2013                     |                | Px        | 74177            |     | Facility           | 1     | Ct Abdoen & Pelvis W/Contrast Material     |                        |             |     |                                | TEDN   | 299    |
| 543         | 356             | 06/14/2013                     |                | Px        | 80053            |     | Facility           | 1     | Comprehensive Metabolic Panel              |                        |             |     |                                | TEDN   | 300    |
| 544         | 356             | 06/14/2013                     |                | Px        | 81001            |     | Facility           | 1     | Urnl's Dip Stick/Tablet Reagent Auto Micro |                        |             |     |                                | TEDN   | 301    |
| 545         | 356             | 06/14/2013                     |                | Px        | 83605            |     | Facility           | 1     | Lactate                                    |                        |             |     |                                | TEDN   | 302    |
| 546         | 356             | 06/14/2013                     |                | Px        | 85025            |     | Facility           | 1     | Blood Count Complete Auto&auto Difrn'l Wb  |                        |             |     |                                | TEDN   | 303    |
| 547         | 356             | 06/14/2013                     |                | Px        | 85610            |     | Facility           | 1     | Prothrombin Time                           |                        |             |     |                                | TEDN   | 304    |
| 548         | 356             | 06/14/2013                     |                | Px        | 85730            |     | Facility           | 1     | Thromboplastin Time Partial Plasma/Whole   |                        |             |     |                                | TEDN   | 305    |
| 549         | 356             | 06/14/2013                     |                | Px        | 87077            |     | Facility           | 1     | Cul Bact Aerobic Add'l Meths Definitive Ea |                        |             |     |                                | TEDN   | 306    |
| 550         | 356             | 06/14/2013                     |                | Px        | 87086            |     | Facility           | 1     | Culture Bacterial Quanttative Colony Coun  |                        |             |     |                                | TEDN   | 307    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 551         | 356             | 06/14/2013                     |                | Px        | 87186       |     | Facility           | 1     | Susceptibly Stdy Antimicrobial Micro/Agar |                             |             |     |                              | TEDN   | 308    |
| 552         | 356             | 06/14/2013                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                             |             |     |                              | TEDN   | 309    |
| 553         | 356             | 06/14/2013                     |                | Px        | 99285       |     | Facility           | 1     | Emergency Dept Visit High Severity&threat |                             |             |     |                              | TEDN   | 310    |
| 554         | 356             | 06/14/2013                     |                | Dx        | 78909       |     | Radio              | 1     | Abdominal Pain Other Site                 |                             |             |     |                              | TEDN   | 311    |
| 555         | 356             | 06/14/2013                     |                | Dx        | 56400       |     | Radio              | 2     | Unspec Constipation                       |                             |             |     |                              | TEDN   | 311    |
| 556         | 356             | 06/14/2013                     |                | Dx        | 6259        |     | Radio              | 3     | Uns Symptom Female Genital Organs         |                             |             |     |                              | TEDN   | 311    |
| 557         | 356             | 06/14/2013                     |                | Px        | 74177       |     | Radio              | 1     | Ct Abdoen & Pelvis W/Contrast Material    |                             |             |     |                              | TEDN   | 311    |
| 558         | 356             | 06/14/2013                     |                | Rx        | 43598022114 |     |                    |       |                                           | Amox Tr-Potassium Clavulana | 10          | 20  | Tablet                       | PDTS   | 297    |
| 559         | 360             | 06/18/2013                     |                | Dx        | 42731       |     | Grppract           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 312    |
| 560         | 360             | 06/18/2013                     |                | Dx        | 4011        |     | Grppract           | 2     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 312    |
| 561         | 360             | 06/18/2013                     |                | Dx        | 2449        |     | Grppract           | 3     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 312    |
| 562         | 360             | 06/18/2013                     |                | Px        | 93040       |     | Grppract           | 1     | Rhythm Ecg 1-3 Leads W/Interpretation & R |                             |             |     |                              | TEDN   | 312    |
| 563         | 360             | 06/18/2013                     |                | Px        | 99213       |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 313    |
| 564         | 378             | 07/06/2013                     |                | Rx        | 51672402703 |     |                    |       |                                           | Warfarin Sodium             | 90          | 180 | Tablet                       | PDTS   | 314    |
| 565         | 378             | 07/06/2013                     |                | Rx        | 68645028254 |     |                    |       |                                           | Citalopram Hbr              | 30          | 30  | Tablet                       | PDTS   | 315    |
| 566         | 388             | 07/16/2013                     |                | Dx        | 45111       |     | Intmed             | 1     | Phlebitis Femoral Vein                    |                             |             |     |                              | TEDN   | 320    |
| 567         | 388             | 07/16/2013                     |                | Dx        | 42731       |     | Intmed             | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 320    |
| 568         | 388             | 07/16/2013                     |                | Px        | 99211       |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 320    |
| 569         | 388             | 07/16/2013                     |                | Rx        | 63304062410 |     |                    |       |                                           | Furosemide                  | 90          | 90  | Tablet                       | PDTS   | 316    |
| 570         | 388             | 07/16/2013                     |                | Rx        | 00591040810 |     |                    |       |                                           | Lisinopril                  | 90          | 90  | Tablet                       | PDTS   | 317    |
| 571         | 388             | 07/16/2013                     |                | Rx        | 53489021510 |     |                    |       |                                           | Clonidine Hcl               | 90          | 90  | Tablet                       | PDTS   | 318    |
| 572         | 388             | 07/16/2013                     |                | Rx        | 55111015810 |     |                    |       |                                           | Omeprazole                  | 30          | 30  | Capsule, DR (Enteric Coated) | PDTS   | 319    |
| 573         | 389             | 07/17/2013                     |                | Dx        | 9596        |     | Ambul              | 1     | Oth/Uns Injury Hip/Thigh                  |                             |             |     |                              | TEDN   | 328    |
| 574         | 389             | 07/17/2013                     |                | Px        | A0425       |     | Ambul              | 1     | Ground Mileage                            |                             |             |     |                              | TEDN   | 328    |
| 575         | 389             | 07/17/2013                     |                | Px        | A0427       |     | Ambul              | 1     | Als1-Emergency                            |                             |             |     |                              | TEDN   | 329    |
| 576         | 389             | 07/17/2013                     |                | Dx        | 82009       |     | Gp                 | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDN   | 321    |
| 577         | 389             | 07/17/2013                     |                | Dx        | 7197        |     | Gp                 | 2     | Difficulty In Walking                     |                             |             |     |                              | TEDN   | 321    |
| 578         | 389             | 07/17/2013                     |                | Dx        | 4019        |     | Gp                 | 3     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 321    |
| 579         | 389             | 07/17/2013                     |                | Dx        | E8888       |     | Gp                 | 4     | Other Fall                                |                             |             |     |                              | TEDN   | 321    |
| 580         | 389             | 07/17/2013                     |                | Px        | 99285       |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                             |             |     |                              | TEDN   | 321    |
| 581         | 389             | 07/17/2013                     |                | Dx        | 82009       |     | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDN   | 322    |
| 582         | 389             | 07/17/2013                     |                | Dx        | E8889       |     | Radio              | 2     | Unspecified Fall                          |                             |             |     |                              | TEDN   | 322    |
| 583         | 389             | 07/17/2013                     |                | Dx        | 71945       |     | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                             |             |     |                              | TEDN   | 322    |
| 584         | 389             | 07/17/2013                     |                | Px        | 72170       |     | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                             |             |     |                              | TEDN   | 322    |
| 585         | 389             | 07/17/2013                     |                | Px        | 73510       |     | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                             |             |     |                              | TEDN   | 323    |
| 586         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 82009       |     |                    | 1     | Fracture Femur Intrcaps Ot Closed         |                             |             |     |                              | TEDI   | 330    |
| 587         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 51881       |     |                    | 2     | Respiratory Failure                       |                             |             |     |                              | TEDI   | 330    |
| 588         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 78550       |     |                    | 3     | Shock Unspecified                         |                             |             |     |                              | TEDI   | 330    |
| 589         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 570         |     |                    | 4     | Acute/Subacute Necrosis Liver             |                             |             |     |                              | TEDI   | 330    |
| 590         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 45381       |     |                    | 5     | Ac Emb/Throm Superficial Upper Ext        |                             |             |     |                              | TEDI   | 330    |
| 591         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 41401       |     |                    | 6     | Atheroscler Native Coronary Art           |                             |             |     |                              | TEDI   | 330    |
| 592         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 42731       |     |                    | 7     | Atrial Fibrillation                       |                             |             |     |                              | TEDI   | 330    |
| 593         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 5939        |     |                    | 8     | Uns Disorder Kidney/Ureter                |                             |             |     |                              | TEDI   | 330    |
| 594         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 2875        |     |                    | 9     | Uns Thrombocytopenia                      |                             |             |     |                              | TEDI   | 330    |
| 595         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 725         |     |                    | 10    | Polymyalgia Rheumatica                    |                             |             |     |                              | TEDI   | 330    |
| 596         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 7102        |     |                    | 11    | Sicca Syndrome                            |                             |             |     |                              | TEDI   | 330    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 597         | 389             | 07/17/2013                     | 07/26/2013     | Dx        | 78079 |      |                    | 12    | Other Malaise And Fatigue                 |                        |             |     |                  | TEDI   | 330    |
| 598         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 7935  |      |                    | 1     | Open Reduction Int Fix Femur              |                        |             |     |                  | TEDI   | 330    |
| 599         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 3897  |      |                    | 2     | Central Line Placement W Guidance         |                        |             |     |                  | TEDI   | 330    |
| 600         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 0017  |      |                    | 3     | Infusion Of Vasopressor Agent             |                        |             |     |                  | TEDI   | 330    |
| 601         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 9907  |      |                    | 4     | Transfusion Of Other Serum                |                        |             |     |                  | TEDI   | 330    |
| 602         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 9904  |      |                    | 5     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 330    |
| 603         | 389             | 07/17/2013                     | 07/26/2013     | Px        | 5794  |      |                    | 6     | Insertion Indwelling Cath                 |                        |             |     |                  | TEDI   | 330    |
| 604         | 389             | 07/17/2013                     |                | Dx        | 82009 | Inpt | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                  | TEDN   | 324    |
| 605         | 389             | 07/17/2013                     |                | Dx        | V4589 | Inpt | Radio              | 2     | Oth Postsurgical Status                   |                        |             |     |                  | TEDN   | 324    |
| 606         | 389             | 07/17/2013                     |                | Px        | 73500 | Inpt | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 324    |
| 607         | 389             | 07/17/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 325    |
| 608         | 389             | 07/17/2013                     |                | Px        | 01220 | Inpt | Anesth             | 1     | Anesthesia Closed Procedures Upper 2/3 Fe |                        |             |     |                  | TEDN   | 325    |
| 609         | 389             | 07/17/2013                     |                | Dx        | 82100 | Inpt | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 326    |
| 610         | 389             | 07/17/2013                     |                | Px        | 27236 | Inpt | Ortho              | 1     | Optx Fem Fx Prox End Nck Int Fixj/Prostc  |                        |             |     |                  | TEDN   | 326    |
| 611         | 389             | 07/17/2013                     |                | Px        | 99223 | Inpt | Ortho              | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 327    |
| 612         | 390             | 07/18/2013                     |                | Dx        | 82009 | Inpt | Grppract           | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                  | TEDN   | 331    |
| 613         | 390             | 07/18/2013                     |                | Dx        | 51881 | Inpt | Grppract           | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 331    |
| 614         | 390             | 07/18/2013                     |                | Dx        | 78550 | Inpt | Grppract           | 3     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 331    |
| 615         | 390             | 07/18/2013                     |                | Dx        | 570   | Inpt | Grppract           | 4     | Acute/Subacute Necrosis Liver             |                        |             |     |                  | TEDN   | 331    |
| 616         | 390             | 07/18/2013                     |                | Px        | 93010 | Inpt | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 331    |
| 617         | 391             | 07/19/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 1     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 332    |
| 618         | 391             | 07/19/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 332    |
| 619         | 391             | 07/19/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 3     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 332    |
| 620         | 391             | 07/19/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 332    |
| 621         | 392             | 07/20/2013                     |                | Dx        | 5180  | Inpt | Radio              | 1     | Pulmonary Collapse                        |                        |             |     |                  | TEDN   | 333    |
| 622         | 392             | 07/20/2013                     |                | Dx        | 5119  | Inpt | Radio              | 2     | Unspecif Pleural Effusion                 |                        |             |     |                  | TEDN   | 333    |
| 623         | 392             | 07/20/2013                     |                | Px        | 71275 | Inpt | Radio              | 1     | Ct Angiography Chest W/Contrast/Noncontra |                        |             |     |                  | TEDN   | 333    |
| 624         | 392             | 07/20/2013                     |                | Dx        | 78550 | Inpt | Pulmo              | 1     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 334    |
| 625         | 392             | 07/20/2013                     |                | Dx        | 51881 | Inpt | Pulmo              | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 334    |
| 626         | 392             | 07/20/2013                     |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 334    |
| 627         | 392             | 07/20/2013                     |                | Px        | 99292 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 335    |
| 628         | 392             | 07/20/2013                     |                | Dx        | 78609 | Inpt | Radio              | 1     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 336    |
| 629         | 392             | 07/20/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 336    |
| 630         | 392             | 07/20/2013                     |                | Dx        | V5881 | Inpt | Radio              | 1     | Fitting/Adjust Vascular Catheter          |                        |             |     |                  | TEDN   | 337    |
| 631         | 392             | 07/20/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 337    |
| 632         | 393             | 07/21/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 338    |
| 633         | 393             | 07/21/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 338    |
| 634         | 393             | 07/21/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 338    |
| 635         | 393             | 07/21/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 338    |
| 636         | 393             | 07/21/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 338    |
| 637         | 393             | 07/21/2013                     |                | Dx        | 78609 | Inpt | Radio              | 1     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 339    |
| 638         | 393             | 07/21/2013                     |                | Dx        | 7869  | Inpt | Radio              | 2     | Other Respiratory Symptoms                |                        |             |     |                  | TEDN   | 339    |
| 639         | 393             | 07/21/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 339    |
| 640         | 393             | 07/21/2013                     |                | Dx        | 7906  | Inpt | Radio              | 1     | Oth Abnormal Blood Chemistry              |                        |             |     |                  | TEDN   | 340    |
| 641         | 393             | 07/21/2013                     |                | Dx        | 78550 | Inpt | Radio              | 2     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 340    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 642         | 393             | 07/21/2013                     |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 340    |
| 643         | 393             | 07/21/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 341    |
| 644         | 393             | 07/21/2013                     |                | Px        | 36556 | Inpt | Anesth             | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 341    |
| 645         | 393             | 07/21/2013                     |                | Px        | 76937 | Inpt | Anesth             | 1     | Us Vasc Access Sits Vsl Patency Ndl Entry |                        |             |     |                  | TEDN   | 342    |
| 646         | 394             | 07/22/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 343    |
| 647         | 394             | 07/22/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 343    |
| 648         | 394             | 07/22/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 343    |
| 649         | 394             | 07/22/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 343    |
| 650         | 394             | 07/22/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 343    |
| 651         | 394             | 07/22/2013                     |                | Dx        | 514   | Inpt | Radio              | 1     | Pulmonary Congestion/Hypostasis           |                        |             |     |                  | TEDN   | 344    |
| 652         | 394             | 07/22/2013                     |                | Dx        | 78609 | Inpt | Radio              | 2     | Respiratory Abnormality Ot                |                        |             |     |                  | TEDN   | 344    |
| 653         | 394             | 07/22/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 344    |
| 654         | 394             | 07/22/2013                     |                | Dx        | 78550 | Inpt | Pulmo              | 1     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 345    |
| 655         | 394             | 07/22/2013                     |                | Px        | 99291 | Inpt | Pulmo              | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 345    |
| 656         | 394             | 07/22/2013                     |                | Dx        | 9597  | Inpt | Radio              | 1     | Oth/Uns Injury Knee Leg Ankle/Foot        |                        |             |     |                  | TEDN   | 346    |
| 657         | 394             | 07/22/2013                     |                | Dx        | 71906 | Inpt | Radio              | 2     | Effusion Of Joint Lower Leg               |                        |             |     |                  | TEDN   | 346    |
| 658         | 394             | 07/22/2013                     |                | Dx        | E8889 | Inpt | Radio              | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 346    |
| 659         | 394             | 07/22/2013                     |                | Px        | 73564 | Inpt | Radio              | 1     | Radiologic Exam Knee Complete 4/More View |                        |             |     |                  | TEDN   | 346    |
| 660         | 395             | 07/23/2013                     |                | Dx        | 79902 |      | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 350    |
| 661         | 395             | 07/23/2013                     |                | Px        | E0431 |      | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 350    |
| 662         | 395             | 07/23/2013                     |                | Px        | E1390 |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 351    |
| 663         | 395             | 07/23/2013                     |                | Dx        | 4371  | Inpt | Radio              | 1     | Oth Generalized Ischemic Cv Disease       |                        |             |     |                  | TEDN   | 347    |
| 664         | 395             | 07/23/2013                     |                | Dx        | 3319  | Inpt | Radio              | 2     | Uns Cerebral Degeneration                 |                        |             |     |                  | TEDN   | 347    |
| 665         | 395             | 07/23/2013                     |                | Px        | 70450 | Inpt | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 347    |
| 666         | 395             | 07/23/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 1     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 348    |
| 667         | 395             | 07/23/2013                     |                | Dx        | 41401 | Inpt | Grppract           | 2     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 348    |
| 668         | 395             | 07/23/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 348    |
| 669         | 395             | 07/23/2013                     |                | Dx        | 8208  | Inpt | Grppract           | 4     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 348    |
| 670         | 395             | 07/23/2013                     |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 348    |
| 671         | 395             | 07/23/2013                     |                | Dx        | 5849  | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 349    |
| 672         | 395             | 07/23/2013                     |                | Px        | 99233 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 349    |
| 673         | 395             | 07/23/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 352    |
| 674         | 395             | 07/23/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 2     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 352    |
| 675         | 395             | 07/23/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 352    |
| 676         | 395             | 07/23/2013                     |                | Dx        | 4011  | Inpt | Grppract           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 352    |
| 677         | 395             | 07/23/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 352    |
| 678         | 396             | 07/24/2013                     |                | Dx        | 486   | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 353    |
| 679         | 396             | 07/24/2013                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 353    |
| 680         | 396             | 07/24/2013                     |                | Dx        | 5849  | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                  | TEDN   | 354    |
| 681         | 396             | 07/24/2013                     |                | Px        | 99232 | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 354    |
| 682         | 396             | 07/24/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 355    |
| 683         | 396             | 07/24/2013                     |                | Dx        | 4589  | Inpt | Grppract           | 2     | Hypotension Unspecified                   |                        |             |     |                  | TEDN   | 355    |
| 684         | 396             | 07/24/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 355    |
| 685         | 396             | 07/24/2013                     |                | Dx        | 4011  | Inpt | Grppract           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 355    |
| 686         | 396             | 07/24/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 355    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 687         | 397             | 07/25/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 356    |
| 688         | 397             | 07/25/2013                     |                | Dx        | 4589        | Inpt | Grpract            | 2     | Hypotension Unspecified                   |                        |             |     |                            | TEDN   | 356    |
| 689         | 397             | 07/25/2013                     |                | Dx        | 42731       | Inpt | Grpract            | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 356    |
| 690         | 397             | 07/25/2013                     |                | Dx        | 4011        | Inpt | Grpract            | 4     | Benign Essential Hypertension             |                        |             |     |                            | TEDN   | 356    |
| 691         | 397             | 07/25/2013                     |                | Px        | 99232       | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                            | TEDN   | 356    |
| 692         | 398             | 07/26/2013                     |                | Dx        | 5849        | Inpt | Pulmo              | 1     | Uns Acute Kidney Failure                  |                        |             |     |                            | TEDN   | 360    |
| 693         | 398             | 07/26/2013                     |                | Px        | 99231       | Inpt | Pulmo              | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                            | TEDN   | 360    |
| 694         | 398             | 07/26/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 361    |
| 695         | 398             | 07/26/2013                     |                | Dx        | 4589        | Inpt | Grpract            | 2     | Hypotension Unspecified                   |                        |             |     |                            | TEDN   | 361    |
| 696         | 398             | 07/26/2013                     |                | Dx        | 42731       | Inpt | Grpract            | 3     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 361    |
| 697         | 398             | 07/26/2013                     |                | Dx        | 4011        | Inpt | Grpract            | 4     | Benign Essential Hypertension             |                        |             |     |                            | TEDN   | 361    |
| 698         | 398             | 07/26/2013                     |                | Px        | 99238       | Inpt | Grpract            | 1     | Hospital Discharge Day Management 30 Min/ |                        |             |     |                            | TEDN   | 361    |
| 699         | 398             | 07/26/2013                     |                | Dx        | 4928        |      | Ambul              | 1     | Other Emphysema                           |                        |             |     |                            | TEDN   | 358    |
| 700         | 398             | 07/26/2013                     |                | Dx        | 8208        |      | Ambul              | 2     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 358    |
| 701         | 398             | 07/26/2013                     |                | Dx        | 71945       |      | Ambul              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                            | TEDN   | 358    |
| 702         | 398             | 07/26/2013                     |                | Dx        | 9072        |      | Ambul              | 4     | Late Effect Of Spinal Cord Inj            |                        |             |     |                            | TEDN   | 358    |
| 703         | 398             | 07/26/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                            | TEDN   | 358    |
| 704         | 398             | 07/26/2013                     |                | Px        | A0428       |      | Ambul              | 1     | Bls                                       |                        |             |     |                            | TEDN   | 359    |
| 705         | 398             | 07/26/2013                     |                | Rx        | 49884086702 |      |                    |       |                                           | Dronabinol             | 7           | 40  | Capsule (Hard, Soft, Etc.) | PDTS   | 357    |
| 706         | 401             | 07/29/2013                     |                | Dx        | 8208        |      | Intmed             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 362    |
| 707         | 401             | 07/29/2013                     |                | Dx        | 78559       |      | Intmed             | 2     | Other Shock Without Trauma                |                        |             |     |                            | TEDN   | 362    |
| 708         | 401             | 07/29/2013                     |                | Dx        | 78820       |      | Intmed             | 3     | Retention Of Urine Unspecified            |                        |             |     |                            | TEDN   | 362    |
| 709         | 401             | 07/29/2013                     |                | Px        | 99306       |      | Intmed             | 1     | Initial Nursing Facility Care/Day High Se |                        |             |     |                            | TEDN   | 362    |
| 710         | 403             | 07/31/2013                     |                | Dx        | 8208        |      | Pa                 | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 363    |
| 711         | 403             | 07/31/2013                     |                | Dx        | 33829       |      | Pa                 | 2     | Other Chronic Pain                        |                        |             |     |                            | TEDN   | 363    |
| 712         | 403             | 07/31/2013                     |                | Dx        | 2801        |      | Pa                 | 3     | Iron Def Anemia Inadeq Iron Intake        |                        |             |     |                            | TEDN   | 363    |
| 713         | 403             | 07/31/2013                     |                | Px        | 99310       |      | Pa                 | 1     | Sbsq Nurs Facil Care/Day Unstabl/New Prob |                        |             |     |                            | TEDN   | 363    |
| 714         | 403             | 07/31/2013                     |                | Dx        | 99649       |      | Misce              | 1     | Ot Malfun Int Orthped Device/Grf          |                        |             |     |                            | TEDN   | 364    |
| 715         | 403             | 07/31/2013                     |                | Dx        | 82009       |      | Misce              | 2     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                            | TEDN   | 364    |
| 716         | 403             | 07/31/2013                     |                | Dx        | V5409       |      | Misce              | 3     | Other Aftercare Internal Fix Device       |                        |             |     |                            | TEDN   | 364    |
| 717         | 403             | 07/31/2013                     |                | Px        | 73510       |      | Misce              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                            | TEDN   | 364    |
| 718         | 404             | 08/01/2013                     |                | Dx        | 7813        |      | Ambul              | 1     | Lack Of Coordination                      |                        |             |     |                            | TEDN   | 365    |
| 719         | 404             | 08/01/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                            | TEDN   | 365    |
| 720         | 404             | 08/01/2013                     |                | Px        | A0427       |      | Ambul              | 1     | Als1-Emergency                            |                        |             |     |                            | TEDN   | 366    |
| 721         | 404             | 08/01/2013                     |                | Dx        | 8208        |      | Intmed             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                            | TEDN   | 370    |
| 722         | 404             | 08/01/2013                     |                | Dx        | 78559       |      | Intmed             | 2     | Other Shock Without Trauma                |                        |             |     |                            | TEDN   | 370    |
| 723         | 404             | 08/01/2013                     |                | Dx        | 78820       |      | Intmed             | 3     | Retention Of Urine Unspecified            |                        |             |     |                            | TEDN   | 370    |
| 724         | 404             | 08/01/2013                     |                | Px        | 99308       |      | Intmed             | 1     | Sbsq Nursing Facil Care/Day Minor Complj  |                        |             |     |                            | TEDN   | 370    |
| 725         | 404             | 08/01/2013                     |                | Px        | 99356       |      | Intmed             | 1     | Prolonged Service I/P Req Unit/Floor Time |                        |             |     |                            | TEDN   | 371    |
| 726         | 404             | 08/01/2013                     |                | Dx        | 82009       | Inpt | Radio              | 1     | Fracture Femur Intrcaps Ot Closed         |                        |             |     |                            | TEDN   | 367    |
| 727         | 404             | 08/01/2013                     |                | Dx        | E9289       | Inpt | Radio              | 2     | Uns Accident                              |                        |             |     |                            | TEDN   | 367    |
| 728         | 404             | 08/01/2013                     |                | Dx        | V7282       | Inpt | Radio              | 3     | Preop Respiratory Examination             |                        |             |     |                            | TEDN   | 367    |
| 729         | 404             | 08/01/2013                     |                | Dx        | 4293        | Inpt | Radio              | 4     | Cardiomegaly                              |                        |             |     |                            | TEDN   | 367    |
| 730         | 404             | 08/01/2013                     |                | Px        | 71010       | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                            | TEDN   | 367    |
| 731         | 404             | 08/01/2013                     |                | Px        | 73510       | Inpt | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                            | TEDN   | 368    |
| 732         | 404             | 08/01/2013                     |                | Dx        | 82021       | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                            | TEDN   | 369    |



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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 733         | 404             | 08/01/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 369    |
| 734         | 404             | 08/01/2013                     |                | Px        | 99222 | Inpt | Grpract            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 369    |
| 735         | 405             | 08/02/2013                     |                | Dx        | 71595 | Inpt | Radio              | 1     | Osteoarthritis Unsp Pelvis/Thigh          |                        |             |     |                  | TEDN   | 372    |
| 736         | 405             | 08/02/2013                     |                | Dx        | 71945 | Inpt | Radio              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 372    |
| 737         | 405             | 08/02/2013                     |                | Dx        | V4364 | Inpt | Radio              | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 372    |
| 738         | 405             | 08/02/2013                     |                | Dx        | V5481 | Inpt | Radio              | 4     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 372    |
| 739         | 405             | 08/02/2013                     |                | Px        | 72170 | Inpt | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 372    |
| 740         | 405             | 08/02/2013                     |                | Px        | 73500 | Inpt | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 373    |
| 741         | 405             | 08/02/2013                     |                | Dx        | 82021 | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 374    |
| 742         | 405             | 08/02/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 374    |
| 743         | 405             | 08/02/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 374    |
| 744         | 405             | 08/02/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 375    |
| 745         | 405             | 08/02/2013                     |                | Px        | 01230 | Inpt | Anesth             | 1     | Anesthesia Open Procedures Upper 2/3 Femu |                        |             |     |                  | TEDN   | 375    |
| 746         | 405             | 08/02/2013                     |                | Dx        | 82100 | Inpt | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 376    |
| 747         | 405             | 08/02/2013                     |                | Px        | 27125 | Inpt | Ortho              | 1     | Hemiarthroplasty Hip Partial              |                        |             |     |                  | TEDN   | 376    |
| 748         | 405             | 08/02/2013                     |                | Dx        | V7283 | Inpt | Grpract            | 1     | Other Pre Operative Examination           |                        |             |     |                  | TEDN   | 377    |
| 749         | 405             | 08/02/2013                     |                | Px        | 93010 | Inpt | Grpract            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 377    |
| 750         | 406             | 08/03/2013                     |                | Dx        | 82021 | Inpt | Grpract            | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 378    |
| 751         | 406             | 08/03/2013                     |                | Dx        | 4011  | Inpt | Grpract            | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 378    |
| 752         | 406             | 08/03/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 378    |
| 753         | 408             | 08/05/2013                     |                | Dx        | 27541 | Inpt | Grpract            | 1     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 379    |
| 754         | 408             | 08/05/2013                     |                | Dx        | 2869  | Inpt | Grpract            | 2     | Oth/Uns Coagulation Defects               |                        |             |     |                  | TEDN   | 379    |
| 755         | 408             | 08/05/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 379    |
| 756         | 409             | 08/06/2013                     |                | Dx        | 27541 | Inpt | Grpract            | 1     | Hypocalcemia                              |                        |             |     |                  | TEDN   | 380    |
| 757         | 409             | 08/06/2013                     |                | Dx        | 2869  | Inpt | Grpract            | 2     | Oth/Uns Coagulation Defects               |                        |             |     |                  | TEDN   | 380    |
| 758         | 409             | 08/06/2013                     |                | Px        | 99232 | Inpt | Grpract            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 380    |
| 759         | 409             | 08/06/2013                     |                | Dx        | 7813  |      | Ambul              | 1     | Lack Of Coordination                      |                        |             |     |                  | TEDN   | 381    |
| 760         | 409             | 08/06/2013                     |                | Px        | A0425 |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 381    |
| 761         | 409             | 08/06/2013                     |                | Px        | A0428 |      | Ambul              | 1     | Bls                                       |                        |             |     |                  | TEDN   | 382    |
| 762         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 383    |
| 763         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | V5409 |      |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 383    |
| 764         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 7197  |      |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 383    |
| 765         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 72887 |      |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 383    |
| 766         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 42731 |      |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 383    |
| 767         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 2875  |      |                    | 6     | Uns Thrombocytopenia                      |                        |             |     |                  | TEDI   | 383    |
| 768         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 41400 |      |                    | 7     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDI   | 383    |
| 769         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 7102  |      |                    | 8     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 383    |
| 770         | 409             | 08/06/2013                     | 08/31/2013     | Dx        | 725   |      |                    | 9     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 383    |
| 771         | 412             | 08/09/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 384    |
| 772         | 412             | 08/09/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 384    |
| 773         | 412             | 08/09/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 384    |
| 774         | 412             | 08/09/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 384    |
| 775         | 412             | 08/09/2013                     |                | Px        | 99305 |      | Gp                 | 1     | Initial Nursing Facility Care/Day Moder S |                        |             |     |                  | TEDN   | 384    |
| 776         | 415             | 08/12/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 385    |
| 777         | 415             | 08/12/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 385    |

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| 778         | 415             | 08/12/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 385    |
| 779         | 415             | 08/12/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 385    |
| 780         | 415             | 08/12/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 385    |
| 781         | 418             | 08/15/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 386    |
| 782         | 418             | 08/15/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 386    |
| 783         | 418             | 08/15/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 386    |
| 784         | 418             | 08/15/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 386    |
| 785         | 418             | 08/15/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 386    |
| 786         | 418             | 08/15/2013                     |                | Dx        | 82100 |     | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 387    |
| 787         | 418             | 08/15/2013                     |                | Px        | 72170 |     | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 387    |
| 788         | 418             | 08/15/2013                     |                | Px        | 73500 |     | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 388    |
| 789         | 422             | 08/19/2013                     |                | Dx        | 2931  |     | Clinpsych          | 1     | Subacute Delirium                         |                        |             |     |                  | TEDN   | 389    |
| 790         | 422             | 08/19/2013                     |                | Dx        | 29020 |     | Clinpsych          | 2     | Senile Dementia W Delusional              |                        |             |     |                  | TEDN   | 389    |
| 791         | 422             | 08/19/2013                     |                | Px        | 90791 |     | Clinpsych          | 1     | 90791                                     |                        |             |     |                  | TEDN   | 389    |
| 792         | 422             | 08/19/2013                     |                | Px        | 96118 |     | Clinpsych          | 1     | Nuropsyc Testing Pr Hr W/Pt & Interpj Tim |                        |             |     |                  | TEDN   | 390    |
| 793         | 423             | 08/20/2013                     |                | Dx        | 78820 |     | Grpract            | 1     | Retention Of Urine Unspecified            |                        |             |     |                  | TEDN   | 391    |
| 794         | 423             | 08/20/2013                     |                | Px        | 51798 |     | Grpract            | 1     | Meas Post-Voiding Residual Urine&/Bldr Ca |                        |             |     |                  | TEDN   | 391    |
| 795         | 425             | 08/22/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 392    |
| 796         | 425             | 08/22/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 392    |
| 797         | 425             | 08/22/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 392    |
| 798         | 425             | 08/22/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 392    |
| 799         | 425             | 08/22/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 392    |
| 800         | 426             | 08/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 393    |
| 801         | 426             | 08/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 393    |
| 802         | 426             | 08/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 394    |
| 803         | 432             | 08/29/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 395    |
| 804         | 432             | 08/29/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 395    |
| 805         | 432             | 08/29/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 395    |
| 806         | 432             | 08/29/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 395    |
| 807         | 432             | 08/29/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 395    |
| 808         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | V5789 |     |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 396    |
| 809         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | V5409 |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 396    |
| 810         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 7197  |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 396    |
| 811         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 72887 |     |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 396    |
| 812         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 42731 |     |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 396    |
| 813         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 2875  |     |                    | 6     | Uns Thrombocytopenia                      |                        |             |     |                  | TEDI   | 396    |
| 814         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 41400 |     |                    | 7     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDI   | 396    |
| 815         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 7102  |     |                    | 8     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 396    |
| 816         | 435             | 09/01/2013                     | 09/08/2013     | Dx        | 725   |     |                    | 9     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 396    |
| 817         | 438             | 09/04/2013                     |                | Dx        | 5272  |     | Oto                | 1     | Sialoadenitis                             |                        |             |     |                  | TEDN   | 397    |
| 818         | 438             | 09/04/2013                     |                | Dx        | 4019  |     | Oto                | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 397    |
| 819         | 438             | 09/04/2013                     |                | Dx        | 42731 |     | Oto                | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 397    |
| 820         | 438             | 09/04/2013                     |                | Px        | 99203 |     | Oto                | 1     | Office Outpatient New 30 Minutes          |                        |             |     |                  | TEDN   | 397    |
| 821         | 438             | 09/04/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 398    |
| 822         | 438             | 09/04/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 398    |

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| 823         | 438             | 09/04/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 398    |
| 824         | 438             | 09/04/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 398    |
| 825         | 438             | 09/04/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 398    |
| 826         | 440             | 09/06/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 399    |
| 827         | 440             | 09/06/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 399    |
| 828         | 440             | 09/06/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 399    |
| 829         | 440             | 09/06/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 399    |
| 830         | 440             | 09/06/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 399    |
| 831         | 440             | 09/06/2013                     |                | Dx        | 82100 |      | Ortho              | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 400    |
| 832         | 440             | 09/06/2013                     |                | Px        | 72170 |      | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 400    |
| 833         | 440             | 09/06/2013                     |                | Px        | 73500 |      | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 401    |
| 834         | 442             | 09/08/2013                     |                | Dx        | 4928  |      | Ambul              | 1     | Other Emphysema                           |                        |             |     |                  | TEDN   | 403    |
| 835         | 442             | 09/08/2013                     |                | Dx        | 71945 |      | Ambul              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 403    |
| 836         | 442             | 09/08/2013                     |                | Dx        | 9072  |      | Ambul              | 3     | Late Effect Of Spinal Cord Inj            |                        |             |     |                  | TEDN   | 403    |
| 837         | 442             | 09/08/2013                     |                | Px        | A0425 |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 403    |
| 838         | 442             | 09/08/2013                     |                | Px        | A0427 |      | Ambul              | 1     | Als1-Emergency                            |                        |             |     |                  | TEDN   | 404    |
| 839         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Gp                 | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 405    |
| 840         | 442             | 09/08/2013                     |                | Dx        | 56211 |      | Gp                 | 2     | Diverticulitis Colon                      |                        |             |     |                  | TEDN   | 405    |
| 841         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Gp                 | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 405    |
| 842         | 442             | 09/08/2013                     |                | Px        | 99285 |      | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 405    |
| 843         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Radio              | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 406    |
| 844         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 2     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 406    |
| 845         | 442             | 09/08/2013                     |                | Px        | 72170 |      | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 406    |
| 846         | 442             | 09/08/2013                     |                | Dx        | 8208  |      | Radio              | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 407    |
| 847         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 2     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 407    |
| 848         | 442             | 09/08/2013                     |                | Dx        | 71945 |      | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 407    |
| 849         | 442             | 09/08/2013                     |                | Px        | 72192 |      | Radio              | 1     | Ct Pelvis W/O Contrast Material           |                        |             |     |                  | TEDN   | 407    |
| 850         | 442             | 09/08/2013                     |                | Px        | 73500 |      | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 408    |
| 851         | 442             | 09/08/2013                     |                | Dx        | 95909 |      | Radio              | 1     | Injury Face/Neck                          |                        |             |     |                  | TEDN   | 410    |
| 852         | 442             | 09/08/2013                     |                | Dx        | 7231  |      | Radio              | 2     | Cervicalgia                               |                        |             |     |                  | TEDN   | 410    |
| 853         | 442             | 09/08/2013                     |                | Dx        | E8889 |      | Radio              | 3     | Unspecified Fall                          |                        |             |     |                  | TEDN   | 410    |
| 854         | 442             | 09/08/2013                     |                | Dx        | 95901 |      | Radio              | 4     | Uns Head Injury                           |                        |             |     |                  | TEDN   | 410    |
| 855         | 442             | 09/08/2013                     |                | Px        | 70450 |      | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 410    |
| 856         | 442             | 09/08/2013                     |                | Px        | 72125 |      | Radio              | 1     | Ct Cervical Spine W/O Contrast Material   |                        |             |     |                  | TEDN   | 411    |
| 857         | 442             | 09/08/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 402    |
| 858         | 442             | 09/08/2013                     |                | Dx        | V5865 | Inpt | Grppract           | 2     | Long-Term Use Steroids                    |                        |             |     |                  | TEDN   | 402    |
| 859         | 442             | 09/08/2013                     |                | Dx        | V5861 | Inpt | Grppract           | 3     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 402    |
| 860         | 442             | 09/08/2013                     |                | Dx        | V4986 | Inpt | Grppract           | 4     | Do Not Resuscitate Status                 |                        |             |     |                  | TEDN   | 402    |
| 861         | 442             | 09/08/2013                     |                | Px        | 99223 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 402    |
| 862         | 442             | 09/08/2013                     |                | Dx        | 82100 | Inpt | Grppract           | 1     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 409    |
| 863         | 442             | 09/08/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 409    |
| 864         | 443             | 09/09/2013                     |                | Dx        | 82021 | Inpt | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 412    |
| 865         | 443             | 09/09/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 412    |
| 866         | 443             | 09/09/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 412    |
| 867         | 443             | 09/09/2013                     |                | Dx        | 8208  | Inpt | Anesth             | 1     | Fracture Neck Of Femur Unsp Closed        |                        |             |     |                  | TEDN   | 413    |
| 868         | 443             | 09/09/2013                     |                | Px        | 01230 | Inpt | Anesth             | 1     | Anesthesia Open Procedures Upper 2/3 Femu |                        |             |     |                  | TEDN   | 413    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|-------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 869         | 443             | 09/09/2013                     |                | Dx        | V5481 | Inpt  | Radio              | 1     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 414    |
| 870         | 443             | 09/09/2013                     |                | Dx        | V4364 | Inpt  | Radio              | 2     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 414    |
| 871         | 443             | 09/09/2013                     |                | Dx        | 71945 | Inpt  | Radio              | 3     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 414    |
| 872         | 443             | 09/09/2013                     |                | Px        | 72170 | Inpt  | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 414    |
| 873         | 443             | 09/09/2013                     |                | Px        | 73500 | Inpt  | Radio              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 415    |
| 874         | 444             | 09/10/2013                     |                | Dx        | 82003 | Inpt  | Ortho              | 1     | Fracture Base Femoral Nck Closed          |                        |             |     |                  | TEDN   | 416    |
| 875         | 444             | 09/10/2013                     |                | Px        | 27236 | Inpt  | Ortho              | 1     | Optx Fem Fx Prox End Nck Int Fixj/Prostc  |                        |             |     |                  | TEDN   | 416    |
| 876         | 444             | 09/10/2013                     |                | Px        | 99222 | Inpt  | Ortho              | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 417    |
| 877         | 444             | 09/10/2013                     |                | Dx        | 82021 | Inpt  | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 418    |
| 878         | 444             | 09/10/2013                     |                | Dx        | 42731 | Inpt  | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 418    |
| 879         | 444             | 09/10/2013                     |                | Px        | 99232 | Inpt  | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 418    |
| 880         | 445             | 09/11/2013                     |                | Dx        | 82021 | Inpt  | Grppract           | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 419    |
| 881         | 445             | 09/11/2013                     |                | Dx        | 42731 | Inpt  | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 419    |
| 882         | 445             | 09/11/2013                     |                | Px        | 99232 | Inpt  | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 419    |
| 883         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | V5789 |       |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 420    |
| 884         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7197  |       |                    | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 420    |
| 885         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 72887 |       |                    | 3     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 420    |
| 886         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | V5409 |       |                    | 4     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 420    |
| 887         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7291  |       |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 420    |
| 888         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 725   |       |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 420    |
| 889         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 7102  |       |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 420    |
| 890         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 33829 |       |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 420    |
| 891         | 445             | 09/11/2013                     | 09/30/2013     | Dx        | 73300 |       |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 420    |
| 892         | 446             | 09/12/2013                     |                | Dx        | 82021 | Gp    |                    | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 421    |
| 893         | 446             | 09/12/2013                     |                | Dx        | 42731 | Gp    |                    | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 421    |
| 894         | 446             | 09/12/2013                     |                | Dx        | 725   | Gp    |                    | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 421    |
| 895         | 446             | 09/12/2013                     |                | Dx        | 2449  | Gp    |                    | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 421    |
| 896         | 446             | 09/12/2013                     |                | Px        | 99309 | Gp    |                    | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 421    |
| 897         | 450             | 09/16/2013                     |                | Dx        | 82021 | Gp    |                    | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 422    |
| 898         | 450             | 09/16/2013                     |                | Dx        | 42731 | Gp    |                    | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 422    |
| 899         | 450             | 09/16/2013                     |                | Dx        | 725   | Gp    |                    | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 422    |
| 900         | 450             | 09/16/2013                     |                | Dx        | 2449  | Gp    |                    | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 422    |
| 901         | 450             | 09/16/2013                     |                | Px        | 99309 | Gp    |                    | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 422    |
| 902         | 453             | 09/19/2013                     |                | Dx        | 82021 | Gp    |                    | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 423    |
| 903         | 453             | 09/19/2013                     |                | Dx        | 42731 | Gp    |                    | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 423    |
| 904         | 453             | 09/19/2013                     |                | Dx        | 725   | Gp    |                    | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 423    |
| 905         | 453             | 09/19/2013                     |                | Dx        | 2449  | Gp    |                    | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 423    |
| 906         | 453             | 09/19/2013                     |                | Px        | 99309 | Gp    |                    | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 423    |
| 907         | 457             | 09/23/2013                     |                | Dx        | 79902 | Medic |                    | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 424    |
| 908         | 457             | 09/23/2013                     |                | Px        | E0431 | Medic |                    | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 424    |
| 909         | 457             | 09/23/2013                     |                | Px        | E1390 | Medic |                    | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 425    |
| 910         | 459             | 09/25/2013                     |                | Dx        | 71945 | Ortho |                    | 1     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 426    |
| 911         | 459             | 09/25/2013                     |                | Px        | 72170 | Ortho |                    | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 426    |
| 912         | 459             | 09/25/2013                     |                | Px        | 73500 | Ortho |                    | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 427    |
| 913         | 460             | 09/26/2013                     |                | Dx        | 82003 | Ortho |                    | 1     | Fracture Base Femoral Nck Closed          |                        |             |     |                  | TEDN   | 428    |
| 914         | 460             | 09/26/2013                     |                | Px        | 99213 | Ortho |                    | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                  | TEDN   | 428    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 915         | 460             | 09/26/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 429    |
| 916         | 460             | 09/26/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 429    |
| 917         | 460             | 09/26/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 429    |
| 918         | 460             | 09/26/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 429    |
| 919         | 460             | 09/26/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 429    |
| 920         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 430    |
| 921         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7197  |      |                    | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 430    |
| 922         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 72887 |      |                    | 3     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 430    |
| 923         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | V5409 |      |                    | 4     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 430    |
| 924         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7291  |      |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 430    |
| 925         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 725   |      |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 430    |
| 926         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 7102  |      |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 430    |
| 927         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 33829 |      |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 430    |
| 928         | 465             | 10/01/2013                     | 10/02/2013     | Dx        | 73300 |      |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 430    |
| 929         | 466             | 10/02/2013                     |                | Dx        | 33818 | Inpt | Grppract           | 1     | Other Acute Postoperative Pain            |                        |             |     |                  | TEDN   | 431    |
| 930         | 466             | 10/02/2013                     |                | Dx        | 71945 | Inpt | Grppract           | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 431    |
| 931         | 466             | 10/02/2013                     |                | Px        | 62311 | Inpt | Grppract           | 1     | Njx Dx/Ther Sbst Epidural/Subarach Lumbar |                        |             |     |                  | TEDN   | 431    |
| 932         | 466             | 10/02/2013                     |                | Dx        | 8082  | Inpt | Grppract           | 1     | Closed Fracture Pubis                     |                        |             |     |                  | TEDN   | 432    |
| 933         | 466             | 10/02/2013                     |                | Dx        | 82100 | Inpt | Grppract           | 2     | Fracture Femur Unsp Closed                |                        |             |     |                  | TEDN   | 432    |
| 934         | 466             | 10/02/2013                     |                | Dx        | V4364 | Inpt | Grppract           | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 432    |
| 935         | 466             | 10/02/2013                     |                | Px        | 72170 | Inpt | Grppract           | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 432    |
| 936         | 466             | 10/02/2013                     |                | Dx        | 99640 | Inpt | Ortho              | 1     | Unsp Malfun Int Orthpd Device/Grf         |                        |             |     |                  | TEDN   | 433    |
| 937         | 466             | 10/02/2013                     |                | Px        | 27138 | Inpt | Ortho              | 1     | Revj Tot Hip Arthrp Fem Only W/Wo Algrft  |                        |             |     |                  | TEDN   | 433    |
| 938         | 466             | 10/02/2013                     |                | Dx        | 99647 | Inpt | Grppract           | 1     | Other Malfun Prosthetic Joint             |                        |             |     |                  | TEDN   | 434    |
| 939         | 466             | 10/02/2013                     |                | Dx        | 4019  | Inpt | Grppract           | 2     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDN   | 434    |
| 940         | 466             | 10/02/2013                     |                | Dx        | 41400 | Inpt | Grppract           | 3     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 434    |
| 941         | 466             | 10/02/2013                     |                | Dx        | 2449  | Inpt | Grppract           | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 434    |
| 942         | 466             | 10/02/2013                     |                | Px        | 01215 | Inpt | Grppract           | 1     | Anesthesia Open Revision Total Hip Arthro |                        |             |     |                  | TEDN   | 434    |
| 943         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | V5789 |      |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 436    |
| 944         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | V5409 |      |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 436    |
| 945         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7197  |      |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 436    |
| 946         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 72887 |      |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 436    |
| 947         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7291  |      |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 436    |
| 948         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 725   |      |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 436    |
| 949         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 7102  |      |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 436    |
| 950         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 33829 |      |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 436    |
| 951         | 468             | 10/04/2013                     | 10/31/2013     | Dx        | 73300 |      |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 436    |
| 952         | 468             | 10/04/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 435    |
| 953         | 468             | 10/04/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 435    |
| 954         | 468             | 10/04/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 435    |
| 955         | 468             | 10/04/2013                     |                | Dx        | 2449  |      | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 435    |
| 956         | 468             | 10/04/2013                     |                | Px        | 99309 |      | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 435    |
| 957         | 471             | 10/07/2013                     |                | Dx        | 82021 |      | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 437    |
| 958         | 471             | 10/07/2013                     |                | Dx        | 42731 |      | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 437    |
| 959         | 471             | 10/07/2013                     |                | Dx        | 725   |      | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 437    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 960         | 471             | 10/07/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 437    |
| 961         | 471             | 10/07/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 437    |
| 962         | 474             | 10/10/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 438    |
| 963         | 474             | 10/10/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 438    |
| 964         | 474             | 10/10/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 438    |
| 965         | 474             | 10/10/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 438    |
| 966         | 474             | 10/10/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 438    |
| 967         | 479             | 10/15/2013                     |                | Dx        | 99677 |     | Ortho              | 1     | Complication Ot Joint Prost               |                        |             |     |                  | TEDN   | 439    |
| 968         | 479             | 10/15/2013                     |                | Dx        | 71945 |     | Ortho              | 2     | Pain In Joint Pelvis/Thigh                |                        |             |     |                  | TEDN   | 439    |
| 969         | 479             | 10/15/2013                     |                | Dx        | V5481 |     | Ortho              | 3     | Aftercare Joint Replacement               |                        |             |     |                  | TEDN   | 439    |
| 970         | 479             | 10/15/2013                     |                | Dx        | V4364 |     | Ortho              | 4     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 439    |
| 971         | 479             | 10/15/2013                     |                | Px        | 72170 |     | Ortho              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 439    |
| 972         | 479             | 10/15/2013                     |                | Px        | 73500 |     | Ortho              | 1     | Radex Hip Unilateral 1 View               |                        |             |     |                  | TEDN   | 440    |
| 973         | 482             | 10/18/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 441    |
| 974         | 482             | 10/18/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 441    |
| 975         | 482             | 10/18/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 441    |
| 976         | 482             | 10/18/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 441    |
| 977         | 482             | 10/18/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 441    |
| 978         | 484             | 10/20/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 442    |
| 979         | 484             | 10/20/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 442    |
| 980         | 484             | 10/20/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 442    |
| 981         | 484             | 10/20/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 442    |
| 982         | 484             | 10/20/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 442    |
| 983         | 487             | 10/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 443    |
| 984         | 487             | 10/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 443    |
| 985         | 487             | 10/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 444    |
| 986         | 491             | 10/27/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 445    |
| 987         | 491             | 10/27/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 445    |
| 988         | 491             | 10/27/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 445    |
| 989         | 491             | 10/27/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 445    |
| 990         | 491             | 10/27/2013                     |                | Px        | 99309 |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                  | TEDN   | 445    |
| 991         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | V5789 |     |                    | 1     | Other Rehabilitation Procedure            |                        |             |     |                  | TEDI   | 448    |
| 992         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | V5409 |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDI   | 448    |
| 993         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7197  |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                  | TEDI   | 448    |
| 994         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 72887 |     |                    | 4     | Muscle Weakness                           |                        |             |     |                  | TEDI   | 448    |
| 995         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7291  |     |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                  | TEDI   | 448    |
| 996         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 725   |     |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDI   | 448    |
| 997         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 7102  |     |                    | 7     | Sicca Syndrome                            |                        |             |     |                  | TEDI   | 448    |
| 998         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 33829 |     |                    | 8     | Other Chronic Pain                        |                        |             |     |                  | TEDI   | 448    |
| 999         | 496             | 11/01/2013                     | 11/13/2013     | Dx        | 73300 |     |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                  | TEDI   | 448    |
| 1000        | 496             | 11/01/2013                     |                | Dx        | 3090  |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                  | TEDN   | 446    |
| 1001        | 496             | 11/01/2013                     |                | Px        | 90832 |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                  | TEDN   | 446    |
| 1002        | 496             | 11/01/2013                     |                | Dx        | 82021 |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                  | TEDN   | 447    |
| 1003        | 496             | 11/01/2013                     |                | Dx        | 42731 |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 447    |
| 1004        | 496             | 11/01/2013                     |                | Dx        | 725   |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                  | TEDN   | 447    |
| 1005        | 496             | 11/01/2013                     |                | Dx        | 2449  |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 447    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|-------------------------------|--------|--------|
| 1006        | 496             | 11/01/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 447    |
| 1007        | 502             | 11/07/2013                     |                | Dx        | 3090        |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                               | TEDN   | 449    |
| 1008        | 502             | 11/07/2013                     |                | Px        | 90832       |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                               | TEDN   | 449    |
| 1009        | 503             | 11/08/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 450    |
| 1010        | 503             | 11/08/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 450    |
| 1011        | 503             | 11/08/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 450    |
| 1012        | 503             | 11/08/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 450    |
| 1013        | 503             | 11/08/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 450    |
| 1014        | 506             | 11/11/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 451    |
| 1015        | 506             | 11/11/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 451    |
| 1016        | 506             | 11/11/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 451    |
| 1017        | 506             | 11/11/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 451    |
| 1018        | 506             | 11/11/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 451    |
| 1019        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 56211       |     |                    | 1     | Diverticulitis Colon                      |                        |             |     |                               | TEDI   | 452    |
| 1020        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | V5409       |     |                    | 2     | Other Aftercare Internal Fix Device       |                        |             |     |                               | TEDI   | 452    |
| 1021        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7197        |     |                    | 3     | Difficulty In Walking                     |                        |             |     |                               | TEDI   | 452    |
| 1022        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 72887       |     |                    | 4     | Muscle Weakness                           |                        |             |     |                               | TEDI   | 452    |
| 1023        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7291        |     |                    | 5     | Uns Myalgia/Myositis                      |                        |             |     |                               | TEDI   | 452    |
| 1024        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 725         |     |                    | 6     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDI   | 452    |
| 1025        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 7102        |     |                    | 7     | Sicca Syndrome                            |                        |             |     |                               | TEDI   | 452    |
| 1026        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 33829       |     |                    | 8     | Other Chronic Pain                        |                        |             |     |                               | TEDI   | 452    |
| 1027        | 508             | 11/13/2013                     | 11/26/2013     | Dx        | 73300       |     |                    | 9     | Osteoporosis Unspec                       |                        |             |     |                               | TEDI   | 452    |
| 1028        | 510             | 11/15/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 453    |
| 1029        | 510             | 11/15/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 453    |
| 1030        | 510             | 11/15/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 453    |
| 1031        | 510             | 11/15/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 453    |
| 1032        | 510             | 11/15/2013                     |                | Px        | 99309       |     | Gp                 | 1     | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                               | TEDN   | 453    |
| 1033        | 512             | 11/17/2013                     |                | Dx        | 3090        |     | Clinpsych          | 1     | Adjustment Disorder Depressed             |                        |             |     |                               | TEDN   | 454    |
| 1034        | 512             | 11/17/2013                     |                | Px        | 90832       |     | Clinpsych          | 1     | 90832                                     |                        |             |     |                               | TEDN   | 454    |
| 1035        | 512             | 11/17/2013                     |                | Dx        | 82021       |     | Gp                 | 1     | Intertrochanteric Fracture Closed         |                        |             |     |                               | TEDN   | 455    |
| 1036        | 512             | 11/17/2013                     |                | Dx        | 42731       |     | Gp                 | 2     | Atrial Fibrillation                       |                        |             |     |                               | TEDN   | 455    |
| 1037        | 512             | 11/17/2013                     |                | Dx        | 725         |     | Gp                 | 3     | Polymyalgia Rheumatica                    |                        |             |     |                               | TEDN   | 455    |
| 1038        | 512             | 11/17/2013                     |                | Dx        | 2449        |     | Gp                 | 4     | Uns Hypothyroidism                        |                        |             |     |                               | TEDN   | 455    |
| 1039        | 512             | 11/17/2013                     |                | Px        | 99315       |     | Gp                 | 1     | Nursing Facility Discharge Management 30  |                        |             |     |                               | TEDN   | 455    |
| 1040        | 518             | 11/23/2013                     |                | Dx        | 79902       |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                               | TEDN   | 456    |
| 1041        | 518             | 11/23/2013                     |                | Px        | E0431       |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                               | TEDN   | 456    |
| 1042        | 518             | 11/23/2013                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                               | TEDN   | 457    |
| 1043        | 520             | 11/25/2013                     |                | Dx        | V5409       |     | Medic              | 1     | Other Aftercare Internal Fix Device       |                        |             |     |                               | TEDN   | 458    |
| 1044        | 520             | 11/25/2013                     |                | Dx        | 7197        |     | Medic              | 2     | Difficulty In Walking                     |                        |             |     |                               | TEDN   | 458    |
| 1045        | 520             | 11/25/2013                     |                | Px        | K0001       |     | Medic              | 1     | Standard Wheelchair                       |                        |             |     |                               | TEDN   | 458    |
| 1046        | 522             | 11/27/2013                     |                | Rx        | 00378623305 |     |                    |       |                                           | Citalopram Hbr         | 90          | 90  | Tablet                        | PDTS   | 459    |
| 1047        | 522             | 11/27/2013                     |                | Rx        | 51672402803 |     |                    |       |                                           | Warfarin Sodium        | 90          | 90  | Tablet                        | PDTS   | 460    |
| 1048        | 522             | 11/27/2013                     |                | Rx        | 68180075103 |     |                    |       |                                           | Amlodipine Besylate    | 90          | 90  | Tablet                        | PDTS   | 461    |
| 1049        | 522             | 11/27/2013                     |                | Rx        | 00245005815 |     |                    |       |                                           | Klor-Con M20           | 90          | 90  | Tablet, SR,particles/Crystals | PDTS   | 462    |
| 1050        | 522             | 11/27/2013                     |                | Rx        | 62175018146 |     |                    |       |                                           | Pantoprazole Sodium    | 90          | 90  | Tablet, DR (Enteric Coated)   | PDTS   | 463    |
| 1051        | 522             | 11/27/2013                     |                | Rx        | 68180051503 |     |                    |       |                                           | Lisinopril             | 90          | 90  | Tablet                        | PDTS   | 464    |



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| 1052        | 522             | 11/27/2013                     |                | Rx        | 00054472831      |     |                    |       |                                            | Prednisone             | 70          | 105 | Tablet           | PDTS   | 465    |
| 1053        | 522             | 11/27/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                            | INDEX STUDY DRUG       | 90          |     | INITIAL FILL     | PDTS   | 466    |
| 1054        | 523             | 11/28/2013                     |                | Dx        | 7812             |     | Intmed             | 1     | Abnormality Of Gait                        |                        |             |     |                  | TEDN   | 467    |
| 1055        | 523             | 11/28/2013                     |                | Px        | G0180            |     | Intmed             | 1     | Md Certification Hha Patient               |                        |             |     |                  | TEDN   | 467    |
| 1056        | 531             | 12/06/2013                     |                | Dx        | 4371             |     | Grpract            | 1     | Oth Generalized Ischemic Cv Disease        |                        |             |     |                  | TEDN   | 468    |
| 1057        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Grpract            | 2     | Headache                                   |                        |             |     |                  | TEDN   | 468    |
| 1058        | 531             | 12/06/2013                     |                | Dx        | 3319             |     | Grpract            | 3     | Uns Cerebral Degeneration                  |                        |             |     |                  | TEDN   | 468    |
| 1059        | 531             | 12/06/2013                     |                | Px        | 70450            |     | Grpract            | 1     | Ct Head/Brain W/O Contrast Material        |                        |             |     |                  | TEDN   | 468    |
| 1060        | 531             | 12/06/2013                     |                | Dx        | 7245             |     | Ambul              | 1     | Backache Unspecified                       |                        |             |     |                  | TEDN   | 469    |
| 1061        | 531             | 12/06/2013                     |                | Px        | A0425            |     | Ambul              | 1     | Ground Mileage                             |                        |             |     |                  | TEDN   | 469    |
| 1062        | 531             | 12/06/2013                     |                | Px        | A0427            |     | Ambul              | 1     | Als1-Emergency                             |                        |             |     |                  | TEDN   | 470    |
| 1063        | 531             | 12/06/2013                     |                | Dx        | 7245             |     | Facility           | 1     | Backache Unspecified                       |                        |             |     |                  | TEDN   | 471    |
| 1064        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Facility           | 2     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 471    |
| 1065        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Facility           | 3     | Headache                                   |                        |             |     |                  | TEDN   | 471    |
| 1066        | 531             | 12/06/2013                     |                | Dx        | 73313            |     | Facility           | 4     | Pathological Fracture Vertebrae            |                        |             |     |                  | TEDN   | 471    |
| 1067        | 531             | 12/06/2013                     |                | Dx        | V5861            |     | Facility           | 5     | Encounter Long Term Anticoagulant          |                        |             |     |                  | TEDN   | 471    |
| 1068        | 531             | 12/06/2013                     |                | Dx        | 7102             |     | Facility           | 6     | Sicca Syndrome                             |                        |             |     |                  | TEDN   | 471    |
| 1069        | 531             | 12/06/2013                     |                | Dx        | 53081            |     | Facility           | 7     | Esophageal Reflux                          |                        |             |     |                  | TEDN   | 471    |
| 1070        | 531             | 12/06/2013                     |                | Dx        | 2724             |     | Facility           | 8     | Oth/Uns Hyperlipidemia                     |                        |             |     |                  | TEDN   | 471    |
| 1071        | 531             | 12/06/2013                     |                | Px        | 36415            |     | Facility           | 1     | Collection Venous Blood Venipuncture       |                        |             |     |                  | TEDN   | 471    |
| 1072        | 531             | 12/06/2013                     |                | Px        | 70450            |     | Facility           | 1     | Ct Head/Brain W/O Contrast Material        |                        |             |     |                  | TEDN   | 472    |
| 1073        | 531             | 12/06/2013                     |                | Px        | 71020            |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat  |                        |             |     |                  | TEDN   | 473    |
| 1074        | 531             | 12/06/2013                     |                | Px        | 80048            |     | Facility           | 1     | Basic Metabolic Panel Calcium Total        |                        |             |     |                  | TEDN   | 474    |
| 1075        | 531             | 12/06/2013                     |                | Px        | 83735            |     | Facility           | 1     | Magnesium                                  |                        |             |     |                  | TEDN   | 475    |
| 1076        | 531             | 12/06/2013                     |                | Px        | 84484            |     | Facility           | 1     | Troponin Quantitative                      |                        |             |     |                  | TEDN   | 476    |
| 1077        | 531             | 12/06/2013                     |                | Px        | 85025            |     | Facility           | 1     | Blood Count Complete Auto&auto Difrntl Wb  |                        |             |     |                  | TEDN   | 477    |
| 1078        | 531             | 12/06/2013                     |                | Px        | 85610            |     | Facility           | 1     | Prothrombin Time                           |                        |             |     |                  | TEDN   | 478    |
| 1079        | 531             | 12/06/2013                     |                | Px        | 93005            |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only   |                        |             |     |                  | TEDN   | 479    |
| 1080        | 531             | 12/06/2013                     |                | Px        | 96374            |     | Facility           | 1     | Ther Proph/Dx Njx Iv Push Single/1st Sbstd |                        |             |     |                  | TEDN   | 480    |
| 1081        | 531             | 12/06/2013                     |                | Px        | 99285            |     | Facility           | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                  | TEDN   | 481    |
| 1082        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Gp                 | 1     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 482    |
| 1083        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Gp                 | 2     | Headache                                   |                        |             |     |                  | TEDN   | 482    |
| 1084        | 531             | 12/06/2013                     |                | Dx        | 8052             |     | Gp                 | 3     | Fracture Dorsal Vertebra Close             |                        |             |     |                  | TEDN   | 482    |
| 1085        | 531             | 12/06/2013                     |                | Px        | 93010            |     | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only    |                        |             |     |                  | TEDN   | 482    |
| 1086        | 531             | 12/06/2013                     |                | Px        | 99285            |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat  |                        |             |     |                  | TEDN   | 483    |
| 1087        | 531             | 12/06/2013                     |                | Dx        | 8052             |     | Radio              | 1     | Fracture Dorsal Vertebra Close             |                        |             |     |                  | TEDN   | 484    |
| 1088        | 531             | 12/06/2013                     |                | Dx        | 78650            |     | Radio              | 2     | Unspec Chest Pain                          |                        |             |     |                  | TEDN   | 484    |
| 1089        | 531             | 12/06/2013                     |                | Dx        | 7840             |     | Radio              | 3     | Headache                                   |                        |             |     |                  | TEDN   | 484    |
| 1090        | 531             | 12/06/2013                     |                | Dx        | E9289            |     | Radio              | 4     | Uns Accident                               |                        |             |     |                  | TEDN   | 484    |
| 1091        | 531             | 12/06/2013                     |                | Px        | 71020            |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat  |                        |             |     |                  | TEDN   | 484    |
| 1092        | 535             | 12/10/2013                     |                | Rx        | 65162062750      |     |                    |       |                                            | Tramadol Hcl           | 33          | 100 | Tablet           | PDTS   | 485    |
| 1093        | 542             | 12/17/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                  | TEDN   | 486    |
| 1094        | 542             | 12/17/2013                     |                | Dx        | 42731            |     | Intmed             | 2     | Atrial Fibrillation                        |                        |             |     |                  | TEDN   | 486    |
| 1095        | 542             | 12/17/2013                     |                | Px        | 85610            |     | Intmed             | 1     | Prothrombin Time                           |                        |             |     |                  | TEDN   | 486    |
| 1096        | 542             | 12/17/2013                     |                | Px        | 99211            |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes          |                        |             |     |                  | TEDN   | 487    |
| 1097        | 545             | 12/20/2013                     |                | Dx        | 45111            |     | Intmed             | 1     | Phlebitis Femoral Vein                     |                        |             |     |                  | TEDN   | 488    |



Patient ID: SLD-0126

Age: 81 Gender: F Indexdate: 06/23/2012 Event Date: 07/17/2013 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code  | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 1098        | 545             | 12/20/2013                     |                | Px        | 85610 |     | Intmed             | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 488    |
| 1099        | 545             | 12/20/2013                     |                | Px        | 99211 |     | Intmed             | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 489    |
| 1100        | 548             | 12/23/2013                     |                | Dx        | 79902 |     | Medic              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 490    |
| 1101        | 548             | 12/23/2013                     |                | Px        | E0431 |     | Medic              | 1     | Portable Gaseous O2                       |                        |             |     |                  | TEDN   | 490    |
| 1102        | 548             | 12/23/2013                     |                | Px        | E1390 |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 491    |
| 1103        | 550             | 12/25/2013                     |                | Dx        | V5409 |     | Medic              | 1     | Other Aftercare Internal Fix Device       |                        |             |     |                  | TEDN   | 492    |
| 1104        | 550             | 12/25/2013                     |                | Dx        | 7197  |     | Medic              | 2     | Difficulty In Walking                     |                        |             |     |                  | TEDN   | 492    |
| 1105        | 550             | 12/25/2013                     |                | Px        | K0001 |     | Medic              | 1     | Standard Wheelchair                       |                        |             |     |                  | TEDN   | 492    |
| 1106        | 570             | 01/14/2014                     |                | Dx        | 8470  |     | Gp                 | 1     | Sprain/Strain Of Neck                     |                        |             |     |                  | TEDN   | 493    |
| 1107        | 570             | 01/14/2014                     |                | Dx        | 92401 |     | Gp                 | 2     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 493    |
| 1108        | 570             | 01/14/2014                     |                | Dx        | 2859  |     | Gp                 | 3     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 493    |
| 1109        | 570             | 01/14/2014                     |                | Dx        | E8129 |     | Gp                 | 4     | Mva Collis Unsp Pers Unspec               |                        |             |     |                  | TEDN   | 493    |
| 1110        | 570             | 01/14/2014                     |                | Px        | 99285 |     | Gp                 | 1     | Emergency Dept Visit High Severity&threat |                        |             |     |                  | TEDN   | 493    |
| 1111        | 570             | 01/14/2014                     |                | Dx        | 92401 |     | Grppract           | 1     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 494    |
| 1112        | 570             | 01/14/2014                     |                | Dx        | 2859  |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 494    |
| 1113        | 570             | 01/14/2014                     |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 494    |
| 1114        | 570             | 01/14/2014                     |                | Dx        | 41400 |     | Grppract           | 4     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 494    |
| 1115        | 570             | 01/14/2014                     |                | Px        | 99220 |     | Grppract           | 1     | Initial Observation Care/Day High Severit |                        |             |     |                  | TEDN   | 494    |
| 1116        | 570             | 01/14/2014                     |                | Dx        | 95901 |     | Radio              | 1     | Uns Head Injury                           |                        |             |     |                  | TEDN   | 495    |
| 1117        | 570             | 01/14/2014                     |                | Dx        | 3319  |     | Radio              | 2     | Uns Cerebral Degeneration                 |                        |             |     |                  | TEDN   | 495    |
| 1118        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 3     | Uns Accident                              |                        |             |     |                  | TEDN   | 495    |
| 1119        | 570             | 01/14/2014                     |                | Px        | 70450 |     | Radio              | 1     | Ct Head/Brain W/O Contrast Material       |                        |             |     |                  | TEDN   | 495    |
| 1120        | 570             | 01/14/2014                     |                | Dx        | 95909 |     | Radio              | 1     | Injury Face/Neck                          |                        |             |     |                  | TEDN   | 496    |
| 1121        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 2     | Uns Accident                              |                        |             |     |                  | TEDN   | 496    |
| 1122        | 570             | 01/14/2014                     |                | Px        | 72020 |     | Radio              | 1     | Radex Spine 1 View Specify Level          |                        |             |     |                  | TEDN   | 496    |
| 1123        | 570             | 01/14/2014                     |                | Px        | 72050 |     | Radio              | 1     | Radex Spine Cervical Minimum 4 Views      |                        |             |     |                  | TEDN   | 497    |
| 1124        | 570             | 01/14/2014                     |                | Dx        | 9596  |     | Radio              | 1     | Oth/Uns Injury Hip/Thigh                  |                        |             |     |                  | TEDN   | 498    |
| 1125        | 570             | 01/14/2014                     |                | Dx        | 95919 |     | Radio              | 2     | Other Injury Other Sites Of Trunk         |                        |             |     |                  | TEDN   | 498    |
| 1126        | 570             | 01/14/2014                     |                | Dx        | V4364 |     | Radio              | 3     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 498    |
| 1127        | 570             | 01/14/2014                     |                | Dx        | E9289 |     | Radio              | 4     | Uns Accident                              |                        |             |     |                  | TEDN   | 498    |
| 1128        | 570             | 01/14/2014                     |                | Px        | 72170 |     | Radio              | 1     | Radiologic Examination Pelvis 1/2 Views   |                        |             |     |                  | TEDN   | 498    |
| 1129        | 570             | 01/14/2014                     |                | Dx        | 9596  |     | Radio              | 1     | Oth/Uns Injury Hip/Thigh                  |                        |             |     |                  | TEDN   | 499    |
| 1130        | 570             | 01/14/2014                     |                | Dx        | V4364 |     | Radio              | 2     | Hip Joint Replacement                     |                        |             |     |                  | TEDN   | 499    |
| 1131        | 570             | 01/14/2014                     |                | Dx        | E8199 |     | Radio              | 3     | Mva Uns Injuring Uns Person               |                        |             |     |                  | TEDN   | 499    |
| 1132        | 570             | 01/14/2014                     |                | Px        | 73510 |     | Radio              | 1     | Radex Hip Unilateral Complete Minimum 2 V |                        |             |     |                  | TEDN   | 499    |
| 1133        | 571             | 01/15/2014                     |                | Dx        | 92401 |     | Grppract           | 1     | Contusion Of Hip                          |                        |             |     |                  | TEDN   | 500    |
| 1134        | 571             | 01/15/2014                     |                | Dx        | 2859  |     | Grppract           | 2     | Anemia Unspecified                        |                        |             |     |                  | TEDN   | 500    |
| 1135        | 571             | 01/15/2014                     |                | Dx        | 42731 |     | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 500    |
| 1136        | 571             | 01/15/2014                     |                | Dx        | 41400 |     | Grppract           | 4     | Coronary Athrscler Uns Vessel             |                        |             |     |                  | TEDN   | 500    |
| 1137        | 571             | 01/15/2014                     |                | Px        | 99225 |     | Grppract           | 1     | Sbsq Observation Care/Day Moderate Severi |                        |             |     |                  | TEDN   | 500    |

End of Profile



Patient ID: ILD-0075

Age: 72 Gender: F Indexdate: 11/01/2013 Event Date: 05/15/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description | Medication Description  | Days Supply | QTY | Drug Formulation           | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|--------------------------------------|-------------------------|-------------|-----|----------------------------|--------|--------|
| 1           | -363            | 11/03/2012                     |                | Dx        | 4659        |      | Fp                 | 1     | Acute Upper Resp Infections Uns      |                         |             |     |                            | TEDN   | 3      |
| 2           | -363            | 11/03/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes   |                         |             |     |                            | TEDN   | 3      |
| 3           | -363            | 11/03/2012                     |                | Rx        | 00781149668 |      |                    |       |                                      | Azithromycin            | 8           | 12  | Tablet                     | PDTS   | 1      |
| 4           | -363            | 11/03/2012                     |                | Rx        | 00603158854 |      |                    |       |                                      | Promethazine Vc-Codeine | 10          | 4   | Syrup                      | PDTS   | 2      |
| 5           | -354            | 11/12/2012                     |                | Rx        | 00603158854 |      |                    |       |                                      | Promethazine Vc-Codeine | 10          | 4   | Syrup                      | PDTS   | 4      |
| 6           | -354            | 11/12/2012                     |                | Rx        | 13668000810 |      |                    |       |                                      | Zolpidem Tartrate       | 30          | 30  | Tablet                     | PDTS   | 5      |
| 7           | -351            | 11/15/2012                     |                | Dx        | 4610        |      | Fp                 | 1     | Acute Maxillary Sinusitis            |                         |             |     |                            | TEDN   | 8      |
| 8           | -351            | 11/15/2012                     |                | Dx        | 71946       |      | Fp                 | 2     | Pain In Joint Lower Leg              |                         |             |     |                            | TEDN   | 8      |
| 9           | -351            | 11/15/2012                     |                | Dx        | 4659        |      | Fp                 | 3     | Acute Upper Resp Infections Uns      |                         |             |     |                            | TEDN   | 8      |
| 10          | -351            | 11/15/2012                     |                | Dx        | 460         |      | Fp                 | 4     | Acute Nasopharyngitis                |                         |             |     |                            | TEDN   | 8      |
| 11          | -351            | 11/15/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes   |                         |             |     |                            | TEDN   | 8      |
| 12          | -351            | 11/15/2012                     |                | Rx        | 59762306001 |      |                    |       |                                      | Azithromycin            | 5           | 12  | Tablet                     | PDTS   | 6      |
| 13          | -351            | 11/15/2012                     |                | Rx        | 00525801990 |      |                    |       |                                      | Metanx                  | 30          | 60  | Tablet                     | PDTS   | 7      |
| 14          | -347            | 11/19/2012                     |                | Dx        | 25060       |      | Podia              | 1     | Diabetes Neuro Manif Type Ii         |                         |             |     |                            | TEDN   | 9      |
| 15          | -347            | 11/19/2012                     |                | Dx        | 1101        |      | Podia              | 2     | Dermatophytosis Nail                 |                         |             |     |                            | TEDN   | 9      |
| 16          | -347            | 11/19/2012                     |                | Dx        | 7812        |      | Podia              | 3     | Abnormality Of Gait                  |                         |             |     |                            | TEDN   | 9      |
| 17          | -347            | 11/19/2012                     |                | Px        | 11721       |      | Podia              | 1     | Debridement Nail Any Method 6/>      |                         |             |     |                            | TEDN   | 9      |
| 18          | -337            | 11/29/2012                     |                | Rx        | 49884040401 |      |                    |       |                                      | Metoprolol Succinate    | 90          | 90  | Tablet, SR 24hr            | PDTS   | 10     |
| 19          | -337            | 11/29/2012                     |                | Rx        | 63653117105 |      |                    |       |                                      | Plavix                  | 90          | 90  | Tablet                     | PDTS   | 11     |
| 20          | -337            | 11/29/2012                     |                | Rx        | 00078037905 |      |                    |       |                                      | Lotrel                  | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 12     |
| 21          | -337            | 11/29/2012                     |                | Rx        | 53746025310 |      |                    |       |                                      | Ranitidine Hcl          | 90          | 360 | Tablet                     | PDTS   | 13     |
| 22          | -337            | 11/29/2012                     |                | Rx        | 00071015823 |      |                    |       |                                      | Lipitor                 | 90          | 90  | Tablet                     | PDTS   | 14     |
| 23          | -337            | 11/29/2012                     |                | Rx        | 00904584940 |      |                    |       |                                      | Metformin Hcl           | 90          | 90  | Tablet                     | PDTS   | 15     |
| 24          | -337            | 11/29/2012                     |                | Rx        | 50111032703 |      |                    |       |                                      | Hydralazine Hcl         | 90          | 180 | Tablet                     | PDTS   | 16     |
| 25          | -327            | 12/09/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 17     |
| 26          | -327            | 12/09/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 17     |
| 27          | -327            | 12/09/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 17     |
| 28          | -327            | 12/09/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 17     |
| 29          | -327            | 12/09/2012                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes |                         |             |     |                            | TEDN   | 17     |
| 30          | -326            | 12/10/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 18     |
| 31          | -326            | 12/10/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 18     |
| 32          | -326            | 12/10/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 18     |
| 33          | -326            | 12/10/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 18     |
| 34          | -326            | 12/10/2012                     |                | Px        | 99233       | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes    |                         |             |     |                            | TEDN   | 18     |
| 35          | -325            | 12/11/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 19     |
| 36          | -325            | 12/11/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 19     |
| 37          | -325            | 12/11/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 19     |
| 38          | -325            | 12/11/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 19     |
| 39          | -325            | 12/11/2012                     |                | Px        | 99232       | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes    |                         |             |     |                            | TEDN   | 19     |
| 40          | -324            | 12/12/2012                     |                | Dx        | 7862        | Inpt | Fp                 | 1     | Cough                                |                         |             |     |                            | TEDN   | 20     |
| 41          | -324            | 12/12/2012                     |                | Dx        | 49121       | Inpt | Fp                 | 2     | Obstruct Chron Bronchitis W Exac     |                         |             |     |                            | TEDN   | 20     |
| 42          | -324            | 12/12/2012                     |                | Dx        | 4280        | Inpt | Fp                 | 3     | Congestive Heart Failure Unspec      |                         |             |     |                            | TEDN   | 20     |
| 43          | -324            | 12/12/2012                     |                | Dx        | 412         | Inpt | Fp                 | 4     | Old Myocardial Infarction            |                         |             |     |                            | TEDN   | 20     |

Patient ID: ILD-0075

Age: 72 Gender: F Indexdate: 11/01/2013 Event Date: 05/15/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS  | Provider Specialty | Seq # | Diagnosis/Procedure Code Description      | Medication Description     | Days Supply | QTY | Drug Formulation | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|------------------|--------|--------|
| 44          | -324            | 12/12/2012                     |                | Px        | 99238       | Inpt | Fp                 | 1     | Hospital Discharge Day Management 30 Min/ |                            |             |     |                  | TEDN   | 20     |
| 45          | -323            | 12/13/2012                     |                | Dx        | 78052       |      | Fp                 | 1     | Insomnia Unspecified                      |                            |             |     |                  | TEDN   | 23     |
| 46          | -323            | 12/13/2012                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 23     |
| 47          | -323            | 12/13/2012                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 21     |
| 48          | -323            | 12/13/2012                     |                | Rx        | 00525801990 |      |                    |       |                                           | Metanx                     | 30          | 60  | Tablet           | PDTS   | 22     |
| 49          | -319            | 12/17/2012                     |                | Dx        | 41401       |      | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                  | TEDN   | 24     |
| 50          | -319            | 12/17/2012                     |                | Dx        | 4011        |      | Cardvasc           | 2     | Benign Essential Hypertension             |                            |             |     |                  | TEDN   | 24     |
| 51          | -319            | 12/17/2012                     |                | Dx        | 2722        |      | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                            |             |     |                  | TEDN   | 24     |
| 52          | -319            | 12/17/2012                     |                | Dx        | 25000       |      | Cardvasc           | 4     | Diabetes Uncompl Type li                  |                            |             |     |                  | TEDN   | 24     |
| 53          | -319            | 12/17/2012                     |                | Px        | 99214       |      | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                  | TEDN   | 24     |
| 54          | -316            | 12/20/2012                     |                | Dx        | 7859        |      | Grpprac            | 1     | Other Cardiovascular Symptoms             |                            |             |     |                  | TEDN   | 25     |
| 55          | -316            | 12/20/2012                     |                | Px        | 93880       |      | Grpprac            | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                            |             |     |                  | TEDN   | 25     |
| 56          | -316            | 12/20/2012                     |                | Dx        | 7859        |      | Facility           | 1     | Other Cardiovascular Symptoms             |                            |             |     |                  | TEDN   | 26     |
| 57          | -316            | 12/20/2012                     |                | Px        | 93880       |      | Facility           | 1     | Duplex Scan Extracranial Art Compl Bi Stu |                            |             |     |                  | TEDN   | 26     |
| 58          | -309            | 12/27/2012                     |                | Rx        | 00168025846 |      |                    |       |                                           | Clotrimazole-Betamethasone | 10          | 45  | Cream (Grams)    | PDTS   | 27     |
| 59          | -305            | 12/31/2012                     |                | Dx        | 460         |      | Grpprac            | 1     | Acute Nasopharyngitis                     |                            |             |     |                  | TEDN   | 31     |
| 60          | -305            | 12/31/2012                     |                | Dx        | 4610        |      | Grpprac            | 2     | Acute Maxillary Sinusitis                 |                            |             |     |                  | TEDN   | 31     |
| 61          | -305            | 12/31/2012                     |                | Px        | 99213       |      | Grpprac            | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 31     |
| 62          | -305            | 12/31/2012                     |                | Rx        | 00603158854 |      |                    |       |                                           | Promethazine Vc-Codeine    | 8           | 120 | Syrup            | PDTS   | 28     |
| 63          | -305            | 12/31/2012                     |                | Rx        | 65862001501 |      |                    |       |                                           | Amoxicillin                | 10          | 20  | Tablet           | PDTS   | 29     |
| 64          | -305            | 12/31/2012                     |                | Rx        | 00603307932 |      |                    |       |                                           | Cyclobenzaprine Hcl        | 10          | 30  | Tablet           | PDTS   | 30     |
| 65          | -291            | 01/14/2013                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 32     |
| 66          | -283            | 01/22/2013                     |                | Dx        | 4610        |      | Fp                 | 1     | Acute Maxillary Sinusitis                 |                            |             |     |                  | TEDN   | 35     |
| 67          | -283            | 01/22/2013                     |                | Dx        | 460         |      | Fp                 | 2     | Acute Nasopharyngitis                     |                            |             |     |                  | TEDN   | 35     |
| 68          | -283            | 01/22/2013                     |                | Dx        | 4659        |      | Fp                 | 3     | Acute Upper Resp Infections Uns           |                            |             |     |                  | TEDN   | 35     |
| 69          | -283            | 01/22/2013                     |                | Dx        | 4660        |      | Fp                 | 4     | Acute Bronchitis                          |                            |             |     |                  | TEDN   | 35     |
| 70          | -283            | 01/22/2013                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                  | TEDN   | 35     |
| 71          | -283            | 01/22/2013                     |                | Rx        | 57664037718 |      |                    |       |                                           | Tramadol Hcl               | 14          | 56  | Tablet           | PDTS   | 33     |
| 72          | -283            | 01/22/2013                     |                | Rx        | 00603158858 |      |                    |       |                                           | Promethazine Vc-Codeine    | 12          | 60  | Syrup            | PDTS   | 34     |
| 73          | -275            | 01/30/2013                     |                | Dx        | 41401       |      | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                  | TEDN   | 36     |
| 74          | -275            | 01/30/2013                     |                | Px        | 78452       |      | Cardvasc           | 1     | Myocardial Spect Multiple Studies         |                            |             |     |                  | TEDN   | 36     |
| 75          | -275            | 01/30/2013                     |                | Px        | 93016       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Phys Sup |                            |             |     |                  | TEDN   | 37     |
| 76          | -275            | 01/30/2013                     |                | Px        | 93017       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Trcg Onl |                            |             |     |                  | TEDN   | 38     |
| 77          | -275            | 01/30/2013                     |                | Px        | 93018       |      | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg I&r Only |                            |             |     |                  | TEDN   | 39     |
| 78          | -275            | 01/30/2013                     |                | Px        | A9502       |      | Cardvasc           | 1     | Tc99m Tetrofosmin                         |                            |             |     |                  | TEDN   | 40     |
| 79          | -267            | 02/07/2013                     |                | Dx        | 8448        |      | Ortho              | 1     | Sprain/Strain Of Knee/Leg Ot              |                            |             |     |                  | TEDN   | 41     |
| 80          | -267            | 02/07/2013                     |                | Dx        | 71514       |      | Ortho              | 2     | Osteoarthritis Local Prim Hand            |                            |             |     |                  | TEDN   | 41     |
| 81          | -267            | 02/07/2013                     |                | Px        | 20600       |      | Ortho              | 1     | Arthrocentesis Aspir&/Injection Small Jt/ |                            |             |     |                  | TEDN   | 41     |
| 82          | -267            | 02/07/2013                     |                | Px        | 99214       |      | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                  | TEDN   | 42     |
| 83          | -267            | 02/07/2013                     |                | Px        | J3301       |      | Ortho              | 1     | Triamcinolone Acet Inj Nos                |                            |             |     |                  | TEDN   | 43     |
| 84          | -261            | 02/13/2013                     |                | Dx        | 71946       |      | Grpprac            | 1     | Pain In Joint Lower Leg                   |                            |             |     |                  | TEDN   | 44     |
| 85          | -261            | 02/13/2013                     |                | Px        | 73562       |      | Grpprac            | 1     | Radiologic Examination Knee 3 Views       |                            |             |     |                  | TEDN   | 44     |
| 86          | -259            | 02/15/2013                     |                | Rx        | 00603646832 |      |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet           | PDTS   | 45     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|---------------------------|-------------|-----|----------------------------|--------|--------|
| 87          | -259            | 02/15/2013                     |                | Rx        | 00591034905 |     |                    |       |                                           | Hydrocodone-Acetaminophen | 15          | 90  | Tablet                     | PDTS   | 46     |
| 88          | -252            | 02/22/2013                     |                | Rx        | 00591551310 |     |                    |       |                                           | Carisoprodol              | 10          | 10  | Tablet                     | PDTS   | 47     |
| 89          | -243            | 03/03/2013                     |                | Dx        | 8472        |     | Fp                 | 1     | Sprain/Strain Lumbar Region               |                           |             |     |                            | TEDN   | 51     |
| 90          | -243            | 03/03/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                            | TEDN   | 51     |
| 91          | -243            | 03/03/2013                     |                | Rx        | 29300012510 |     |                    |       |                                           | Meloxicam                 | 30          | 30  | Tablet                     | PDTS   | 48     |
| 92          | -243            | 03/03/2013                     |                | Rx        | 57664037718 |     |                    |       |                                           | Tramadol Hcl              | 12          | 50  | Tablet                     | PDTS   | 49     |
| 93          | -243            | 03/03/2013                     |                | Rx        | 00591551310 |     |                    |       |                                           | Carisoprodol              | 30          | 50  | Tablet                     | PDTS   | 50     |
| 94          | -227            | 03/19/2013                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                           |             |     |                            | TEDN   | 52     |
| 95          | -227            | 03/19/2013                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                           |             |     |                            | TEDN   | 52     |
| 96          | -227            | 03/19/2013                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                           |             |     |                            | TEDN   | 52     |
| 97          | -227            | 03/19/2013                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type Ii                  |                           |             |     |                            | TEDN   | 52     |
| 98          | -227            | 03/19/2013                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                            | TEDN   | 52     |
| 99          | -223            | 03/23/2013                     |                | Rx        | 59762306001 |     |                    |       |                                           | Azithromycin              | 8           | 12  | Tablet                     | PDTS   | 53     |
| 100         | -223            | 03/23/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate         | 15          | 15  | Tablet                     | PDTS   | 54     |
| 101         | -220            | 03/26/2013                     |                | Dx        | 4659        |     | Fp                 | 1     | Acute Upper Resp Infections Uns           |                           |             |     |                            | TEDN   | 58     |
| 102         | -220            | 03/26/2013                     |                | Dx        | 4660        |     | Fp                 | 2     | Acute Bronchitis                          |                           |             |     |                            | TEDN   | 58     |
| 103         | -220            | 03/26/2013                     |                | Dx        | 4610        |     | Fp                 | 3     | Acute Maxillary Sinusitis                 |                           |             |     |                            | TEDN   | 58     |
| 104         | -220            | 03/26/2013                     |                | Dx        | 4871        |     | Fp                 | 4     | Influenza W Oth Respiratory Manif         |                           |             |     |                            | TEDN   | 58     |
| 105         | -220            | 03/26/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                            | TEDN   | 58     |
| 106         | -220            | 03/26/2013                     |                | Rx        | 00378363705 |     |                    |       |                                           | Cetirizine Hcl            | 30          | 30  | Tablet                     | PDTS   | 55     |
| 107         | -220            | 03/26/2013                     |                | Rx        | 00603158758 |     |                    |       |                                           | Promethazine Vc           | 9           | 180 | Syrup                      | PDTS   | 56     |
| 108         | -220            | 03/26/2013                     |                | Rx        | 00004080085 |     |                    |       |                                           | Tamiflu                   | 5           | 10  | Capsule (Hard, Soft, Etc.) | PDTS   | 57     |
| 109         | -219            | 03/27/2013                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate      | 90          | 90  | Tablet, SR 24hr            | PDTS   | 59     |
| 110         | -219            | 03/27/2013                     |                | Rx        | 54569214000 |     |                    |       |                                           | Nitrostat                 | 30          | 100 | Tablet, Sublingual         | PDTS   | 60     |
| 111         | -219            | 03/27/2013                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                    | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 61     |
| 112         | -219            | 03/27/2013                     |                | Rx        | 00071015823 |     |                    |       |                                           | Lipitor                   | 90          | 90  | Tablet                     | PDTS   | 62     |
| 113         | -219            | 03/27/2013                     |                | Rx        | 50111032703 |     |                    |       |                                           | Hydralazine Hcl           | 90          | 180 | Tablet                     | PDTS   | 63     |
| 114         | -219            | 03/27/2013                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl             | 90          | 90  | Tablet                     | PDTS   | 64     |
| 115         | -219            | 03/27/2013                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl            | 90          | 360 | Tablet                     | PDTS   | 65     |
| 116         | -211            | 04/04/2013                     |                | Dx        | 490         |     | Gp                 | 1     | Bronchitis Unspecified                    |                           |             |     |                            | TEDN   | 69     |
| 117         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Gp                 | 2     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 69     |
| 118         | -211            | 04/04/2013                     |                | Px        | 99284       |     | Gp                 | 1     | Emergency Department Visit High/Urgent Se |                           |             |     |                            | TEDN   | 69     |
| 119         | -211            | 04/04/2013                     |                | Dx        | 7862        |     | Radio              | 1     | Cough                                     |                           |             |     |                            | TEDN   | 70     |
| 120         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Radio              | 2     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 70     |
| 121         | -211            | 04/04/2013                     |                | Px        | 71020       |     | Radio              | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                           |             |     |                            | TEDN   | 70     |
| 122         | -211            | 04/04/2013                     |                | Dx        | 7245        |     | Facility           | 1     | Backache Unspecified                      |                           |             |     |                            | TEDN   | 71     |
| 123         | -211            | 04/04/2013                     |                | Dx        | 4660        |     | Facility           | 2     | Acute Bronchitis                          |                           |             |     |                            | TEDN   | 71     |
| 124         | -211            | 04/04/2013                     |                | Dx        | 412         |     | Facility           | 3     | Old Myocardial Infarction                 |                           |             |     |                            | TEDN   | 71     |
| 125         | -211            | 04/04/2013                     |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                           |             |     |                            | TEDN   | 71     |
| 126         | -211            | 04/04/2013                     |                | Dx        | 25000       |     | Facility           | 5     | Diabetes Uncompl Type Ii                  |                           |             |     |                            | TEDN   | 71     |
| 127         | -211            | 04/04/2013                     |                | Px        | 71020       |     | Facility           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                           |             |     |                            | TEDN   | 71     |
| 128         | -211            | 04/04/2013                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                           |             |     |                            | TEDN   | 72     |
| 129         | -211            | 04/04/2013                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor  |                           |             |     |                            | TEDN   | 73     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|----------------------------|--------|--------|
| 130         | -211            | 04/04/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                            |             |     |                            | TEDN   | 74     |
| 131         | -211            | 04/04/2013                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog              |                            |             |     |                            | TEDN   | 75     |
| 132         | -211            | 04/04/2013                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 3           | 20  | Tablet                     | PDTS   | 66     |
| 133         | -211            | 04/04/2013                     |                | Rx        | 00603533832 |     |                    |       |                                           | Prednisone                 | 21          | 56  | Tablet                     | PDTS   | 67     |
| 134         | -211            | 04/04/2013                     |                | Rx        | 67877010605 |     |                    |       |                                           | Benzonatate                | 8           | 30  | Capsule (Hard, Soft, Etc.) | PDTS   | 68     |
| 135         | -207            | 04/08/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 15          | 15  | Tablet                     | PDTS   | 76     |
| 136         | -206            | 04/09/2013                     |                | Dx        | 4241        |     | Cardvasc           | 1     | Aortic Valve Disorders                    |                            |             |     |                            | TEDN   | 77     |
| 137         | -206            | 04/09/2013                     |                | Px        | 93306       |     | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                            |             |     |                            | TEDN   | 77     |
| 138         | -206            | 04/09/2013                     |                | Dx        | 4241        |     | Facility           | 1     | Aortic Valve Disorders                    |                            |             |     |                            | TEDN   | 78     |
| 139         | -206            | 04/09/2013                     |                | Dx        | 3970        |     | Facility           | 2     | Diseases Tricuspid Valve                  |                            |             |     |                            | TEDN   | 78     |
| 140         | -206            | 04/09/2013                     |                | Px        | 93306       |     | Facility           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                            |             |     |                            | TEDN   | 78     |
| 141         | -202            | 04/13/2013                     |                | Rx        | 31722022205 |     |                    |       |                                           | Gabapentin                 | 30          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 79     |
| 142         | -202            | 04/13/2013                     |                | Rx        | 00603158858 |     |                    |       |                                           | Promethazine Vc-Codeine    | 12          | 60  | Syrup                      | PDTS   | 80     |
| 143         | -186            | 04/29/2013                     |                | Dx        | 7840        |     | Fp                 | 1     | Headache                                  |                            |             |     |                            | TEDN   | 84     |
| 144         | -186            | 04/29/2013                     |                | Dx        | 53081       |     | Fp                 | 2     | Esophageal Reflux                         |                            |             |     |                            | TEDN   | 84     |
| 145         | -186            | 04/29/2013                     |                | Dx        | 78052       |     | Fp                 | 3     | Insomnia Unspecified                      |                            |             |     |                            | TEDN   | 84     |
| 146         | -186            | 04/29/2013                     |                | Dx        | 4610        |     | Fp                 | 4     | Acute Maxillary Sinusitis                 |                            |             |     |                            | TEDN   | 84     |
| 147         | -186            | 04/29/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 84     |
| 148         | -186            | 04/29/2013                     |                | Rx        | 0           |     |                    |       |                                           | Compounded Medication      | 6           | 360 |                            | PDTS   | 81     |
| 149         | -186            | 04/29/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 82     |
| 150         | -186            | 04/29/2013                     |                | Rx        | 60429002230 |     |                    |       |                                           | Amoxicillin                | 10          | 30  | Capsule (Hard, Soft, Etc.) | PDTS   | 83     |
| 151         | -176            | 05/09/2013                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)              | PDTS   | 85     |
| 152         | -162            | 05/23/2013                     |                | Rx        | 55111019605 |     |                    |       |                                           | Clopidogrel                | 60          | 60  | Tablet                     | PDTS   | 86     |
| 153         | -154            | 05/31/2013                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 87     |
| 154         | -153            | 06/01/2013                     |                | Dx        | 25000       |     | Fp                 | 1     | Diabetes Uncompl Type Ii                  |                            |             |     |                            | TEDN   | 88     |
| 155         | -153            | 06/01/2013                     |                | Dx        | 2810        |     | Fp                 | 2     | Pernicious Anemia                         |                            |             |     |                            | TEDN   | 88     |
| 156         | -153            | 06/01/2013                     |                | Dx        | 7295        |     | Fp                 | 3     | Pain In Limb                              |                            |             |     |                            | TEDN   | 88     |
| 157         | -153            | 06/01/2013                     |                | Dx        | 7804        |     | Fp                 | 4     | Dizziness And Giddiness                   |                            |             |     |                            | TEDN   | 88     |
| 158         | -153            | 06/01/2013                     |                | Px        | 80053       |     | Fp                 | 1     | Comprehensive Metabolic Panel             |                            |             |     |                            | TEDN   | 88     |
| 159         | -153            | 06/01/2013                     |                | Px        | 83036       |     | Fp                 | 1     | Hemoglobin Glycosylated A1c               |                            |             |     |                            | TEDN   | 89     |
| 160         | -153            | 06/01/2013                     |                | Px        | 85025       |     | Fp                 | 1     | Blood Count Complete Auto&auto Difrnlt Wb |                            |             |     |                            | TEDN   | 90     |
| 161         | -153            | 06/01/2013                     |                | Px        | 99214       |     | Fp                 | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                            | TEDN   | 91     |
| 162         | -152            | 06/02/2013                     |                | Rx        | 51991060401 |     |                    |       |                                           | Vitamin D2                 | 90          | 12  | Capsule (Hard, Soft, Etc.) | PDTS   | 92     |
| 163         | -144            | 06/10/2013                     |                | Dx        | 25060       |     | Grppract           | 1     | Diabetes Neuro Manif Type Ii              |                            |             |     |                            | TEDN   | 94     |
| 164         | -144            | 06/10/2013                     |                | Dx        | 7030        |     | Grppract           | 2     | Ingrowing Nail                            |                            |             |     |                            | TEDN   | 94     |
| 165         | -144            | 06/10/2013                     |                | Dx        | 1101        |     | Grppract           | 3     | Dermatophytosis Nail                      |                            |             |     |                            | TEDN   | 94     |
| 166         | -144            | 06/10/2013                     |                | Dx        | 7823        |     | Grppract           | 4     | Edema                                     |                            |             |     |                            | TEDN   | 94     |
| 167         | -144            | 06/10/2013                     |                | Dx        | 3556        |     | Grppract           | 5     | Lesion Plantar Nerve                      |                            |             |     |                            | TEDN   | 94     |
| 168         | -144            | 06/10/2013                     |                | Dx        | 73399       |     | Grppract           | 6     | Other Disorders Bone/Cartilage            |                            |             |     |                            | TEDN   | 94     |
| 169         | -144            | 06/10/2013                     |                | Px        | 99213       |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 94     |
| 170         | -144            | 06/10/2013                     |                | Rx        | 0           |     |                    |       |                                           | Compounded Medication      | 6           | 360 |                            | PDTS   | 93     |
| 171         | -143            | 06/11/2013                     |                | Dx        | 71597       |     | Grppract           | 1     | Osteoarthritis Unsp Ankle/Foot            |                            |             |     |                            | TEDN   | 95     |
| 172         | -143            | 06/11/2013                     |                | Dx        | 71947       |     | Grppract           | 2     | Pain In Joint Ankle/Foot                  |                            |             |     |                            | TEDN   | 95     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|--------------------------------------------|-----------------------------|-------------|-----|----------------------------|--------|--------|
| 173         | -143            | 06/11/2013                     |                | Px        | 73630       |     | Grpract            | 1     | Radex Foot Complete Minimum 3 Views        |                             |             |     |                            | TEDN   | 95     |
| 174         | -130            | 06/24/2013                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art            |                             |             |     |                            | TEDN   | 96     |
| 175         | -130            | 06/24/2013                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension              |                             |             |     |                            | TEDN   | 96     |
| 176         | -130            | 06/24/2013                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                       |                             |             |     |                            | TEDN   | 96     |
| 177         | -130            | 06/24/2013                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type Ii                   |                             |             |     |                            | TEDN   | 96     |
| 178         | -130            | 06/24/2013                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes         |                             |             |     |                            | TEDN   | 96     |
| 179         | -129            | 06/25/2013                     |                | Dx        | 25060       |     | Grpract            | 1     | Diabetes Neuro Manif Type Ii               |                             |             |     |                            | TEDN   | 97     |
| 180         | -129            | 06/25/2013                     |                | Dx        | 4019        |     | Grpract            | 2     | Unspecified Essential Hypertension         |                             |             |     |                            | TEDN   | 97     |
| 181         | -129            | 06/25/2013                     |                | Dx        | 78191       |     | Grpract            | 3     | Loss Of Height                             |                             |             |     |                            | TEDN   | 97     |
| 182         | -129            | 06/25/2013                     |                | Dx        | 78079       |     | Grpract            | 4     | Other Malaise And Fatigue                  |                             |             |     |                            | TEDN   | 97     |
| 183         | -129            | 06/25/2013                     |                | Px        | 99204       |     | Grpract            | 1     | Office Outpatient New 45 Minutes           |                             |             |     |                            | TEDN   | 97     |
| 184         | -127            | 06/27/2013                     |                | Rx        | 53746025310 |     |                    |       |                                            | Ranitidine Hcl              | 90          | 360 | Tablet                     | PDTS   | 98     |
| 185         | -127            | 06/27/2013                     |                | Rx        | 00904584940 |     |                    |       |                                            | Metformin Hcl               | 90          | 90  | Tablet                     | PDTS   | 99     |
| 186         | -127            | 06/27/2013                     |                | Rx        | 49884040401 |     |                    |       |                                            | Metoprolol Succinate        | 90          | 90  | Tablet, SR 24hr            | PDTS   | 100    |
| 187         | -127            | 06/27/2013                     |                | Rx        | 50111032703 |     |                    |       |                                            | Hydralazine Hcl             | 90          | 180 | Tablet                     | PDTS   | 101    |
| 188         | -123            | 07/01/2013                     |                | Rx        | 00078040605 |     |                    |       |                                            | Lotrel                      | 90          | 180 | Capsule (Hard, Soft, Etc.) | PDTS   | 102    |
| 189         | -122            | 07/02/2013                     |                | Rx        | 00603646832 |     |                    |       |                                            | Zolpidem Tartrate           | 30          | 30  | Tablet                     | PDTS   | 103    |
| 190         | -116            | 07/08/2013                     |                | Dx        | 25060       |     | Podia              | 1     | Diabetes Neuro Manif Type Ii               |                             |             |     |                            | TEDN   | 104    |
| 191         | -116            | 07/08/2013                     |                | Dx        | 73394       |     | Podia              | 2     | Stress Fracture The Metatarsals            |                             |             |     |                            | TEDN   | 104    |
| 192         | -116            | 07/08/2013                     |                | Px        | 99213       |     | Podia              | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                            | TEDN   | 104    |
| 193         | -105            | 07/19/2013                     |                | Dx        | 7295        |     | Fp                 | 1     | Pain In Limb                               |                             |             |     |                            | TEDN   | 106    |
| 194         | -105            | 07/19/2013                     |                | Dx        | 78831       |     | Fp                 | 2     | Urge Incontinence                          |                             |             |     |                            | TEDN   | 106    |
| 195         | -105            | 07/19/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                            | TEDN   | 106    |
| 196         | -105            | 07/19/2013                     |                | Rx        | 00009519102 |     |                    |       |                                            | Detrol La                   | 30          | 30  | Capsule, SR 24 Hr          | PDTS   | 105    |
| 197         | -95             | 07/29/2013                     |                | Rx        | 00071015823 |     |                    |       |                                            | Lipitor                     | 90          | 90  | Tablet                     | PDTS   | 107    |
| 198         | -91             | 08/02/2013                     |                | Dx        | 5990        |     | Pa                 | 1     | Urinary Tract Infection Unspec             |                             |             |     |                            | TEDN   | 110    |
| 199         | -91             | 08/02/2013                     |                | Dx        | 7245        |     | Pa                 | 2     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 110    |
| 200         | -91             | 08/02/2013                     |                | Px        | 99284       |     | Pa                 | 1     | Emergency Department Visit High/Urgent Se  |                             |             |     |                            | TEDN   | 110    |
| 201         | -91             | 08/02/2013                     |                | Dx        | 7245        |     | Facility           | 1     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 111    |
| 202         | -91             | 08/02/2013                     |                | Dx        | 5990        |     | Facility           | 2     | Urinary Tract Infection Unspec             |                             |             |     |                            | TEDN   | 111    |
| 203         | -91             | 08/02/2013                     |                | Dx        | 412         |     | Facility           | 3     | Old Myocardial Infarction                  |                             |             |     |                            | TEDN   | 111    |
| 204         | -91             | 08/02/2013                     |                | Dx        | 41401       |     | Facility           | 4     | Atheroscler Native Coronary Art            |                             |             |     |                            | TEDN   | 111    |
| 205         | -91             | 08/02/2013                     |                | Dx        | 25000       |     | Facility           | 5     | Diabetes Uncompl Type Ii                   |                             |             |     |                            | TEDN   | 111    |
| 206         | -91             | 08/02/2013                     |                | Dx        | 4019        |     | Facility           | 6     | Unspecified Essential Hypertension         |                             |             |     |                            | TEDN   | 111    |
| 207         | -91             | 08/02/2013                     |                | Px        | 81001       |     | Facility           | 1     | Urnlis Dip Stick/Tablet Reagent Auto Micro |                             |             |     |                            | TEDN   | 111    |
| 208         | -91             | 08/02/2013                     |                | Px        | 87086       |     | Facility           | 1     | Culture Bacterial Quanttative Colony Coun  |                             |             |     |                            | TEDN   | 112    |
| 209         | -91             | 08/02/2013                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor   |                             |             |     |                            | TEDN   | 113    |
| 210         | -91             | 08/02/2013                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever  |                             |             |     |                            | TEDN   | 114    |
| 211         | -91             | 08/02/2013                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog               |                             |             |     |                            | TEDN   | 115    |
| 212         | -91             | 08/02/2013                     |                | Rx        | 53746027205 |     |                    |       |                                            | Sulfamethoxazole-Trimethopr | 7           | 14  | Tablet                     | PDTS   | 108    |
| 213         | -91             | 08/02/2013                     |                | Rx        | 00406035705 |     |                    |       |                                            | Hydrocodone-Acetaminophen   | 2           | 14  | Tablet                     | PDTS   | 109    |
| 214         | -86             | 08/07/2013                     |                | Dx        | 7245        |     | Fp                 | 1     | Backache Unspecified                       |                             |             |     |                            | TEDN   | 117    |
| 215         | -86             | 08/07/2013                     |                | Dx        | 5950        |     | Fp                 | 2     | Acute Cystitis                             |                             |             |     |                            | TEDN   | 117    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|----------------------------|--------|--------|
| 216         | -86             | 08/07/2013                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                            | TEDN   | 117    |
| 217         | -86             | 08/07/2013                     |                | Rx        | 63481068706 |     |                    |       |                                           | Lidoderm                   | 30          | 30  | Adhesive Patch, Medicated  | PDTS   | 116    |
| 218         | -84             | 08/09/2013                     |                | Rx        | 60505260401 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 118    |
| 219         | -84             | 08/09/2013                     |                | Rx        | 63653117105 |     |                    |       |                                           | Plavix                     | 90          | 90  | Tablet                     | PDTS   | 119    |
| 220         | -84             | 08/09/2013                     |                | Rx        | 00172531260 |     |                    |       |                                           | Ciprofloxacin Hcl          | 10          | 20  | Tablet                     | PDTS   | 120    |
| 221         | -79             | 08/14/2013                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)              | PDTS   | 121    |
| 222         | -77             | 08/16/2013                     |                | Dx        | 7242        |     | Medic              | 1     | Lumbago                                   |                            |             |     |                            | TEDN   | 122    |
| 223         | -77             | 08/16/2013                     |                | Px        | L0631       |     | Medic              | 1     | Lso Sag-Coro Rigid Frame Pre              |                            |             |     |                            | TEDN   | 122    |
| 224         | -77             | 08/16/2013                     |                | Dx        | 71947       |     | Grppract           | 1     | Pain In Joint Ankle/Foot                  |                            |             |     |                            | TEDN   | 123    |
| 225         | -77             | 08/16/2013                     |                | Dx        | 72981       |     | Grppract           | 2     | Swelling Limb                             |                            |             |     |                            | TEDN   | 123    |
| 226         | -77             | 08/16/2013                     |                | Dx        | 72673       |     | Grppract           | 3     | Calcaneal Spur                            |                            |             |     |                            | TEDN   | 123    |
| 227         | -77             | 08/16/2013                     |                | Px        | 73630       |     | Grppract           | 1     | Radex Foot Complete Minimum 3 Views       |                            |             |     |                            | TEDN   | 123    |
| 228         | -74             | 08/19/2013                     |                | Dx        | 71944       |     | Ortho              | 1     | Pain In Joint Hand                        |                            |             |     |                            | TEDN   | 125    |
| 229         | -74             | 08/19/2013                     |                | Px        | 99214       |     | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                            | TEDN   | 125    |
| 230         | -74             | 08/19/2013                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 10          | 40  | Tablet                     | PDTS   | 124    |
| 231         | -53             | 09/09/2013                     |                | Dx        | 25060       |     | Podia              | 1     | Diabetes Neuro Manif Type Ii              |                            |             |     |                            | TEDN   | 126    |
| 232         | -53             | 09/09/2013                     |                | Dx        | 3560        |     | Podia              | 2     | Hereditary Peripheral Neuropathy          |                            |             |     |                            | TEDN   | 126    |
| 233         | -53             | 09/09/2013                     |                | Dx        | 7030        |     | Podia              | 3     | Ingrowing Nail                            |                            |             |     |                            | TEDN   | 126    |
| 234         | -53             | 09/09/2013                     |                | Dx        | 1101        |     | Podia              | 4     | Dermatophytosis Nail                      |                            |             |     |                            | TEDN   | 126    |
| 235         | -53             | 09/09/2013                     |                | Dx        | 73037       |     | Podia              | 5     | Periostitis Ankle/Foot                    |                            |             |     |                            | TEDN   | 126    |
| 236         | -53             | 09/09/2013                     |                | Px        | 11721       |     | Podia              | 1     | Debridement Nail Any Method 6/>           |                            |             |     |                            | TEDN   | 126    |
| 237         | -51             | 09/11/2013                     |                | Dx        | 71534       |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                            |             |     |                            | TEDN   | 127    |
| 238         | -51             | 09/11/2013                     |                | Px        | 99212       |     | Ortho              | 1     | Office Outpatient Visit 10 Minutes        |                            |             |     |                            | TEDN   | 127    |
| 239         | -50             | 09/12/2013                     |                | Rx        | 00071101468 |     |                    |       |                                           | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 128    |
| 240         | -44             | 09/18/2013                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl              | 90          | 90  | Tablet                     | PDTS   | 129    |
| 241         | -44             | 09/18/2013                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl             | 90          | 360 | Tablet                     | PDTS   | 130    |
| 242         | -44             | 09/18/2013                     |                | Rx        | 60505260401 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                     | PDTS   | 131    |
| 243         | -42             | 09/20/2013                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr            | PDTS   | 132    |
| 244         | -42             | 09/20/2013                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 133    |
| 245         | -38             | 09/24/2013                     |                | Dx        | V7281       |     | Facility           | 1     | Preop Cardiovascular Examination          |                            |             |     |                            | TEDN   | 134    |
| 246         | -38             | 09/24/2013                     |                | Dx        | 71594       |     | Facility           | 2     | Osteoarthritis Unsp Hand                  |                            |             |     |                            | TEDN   | 134    |
| 247         | -38             | 09/24/2013                     |                | Dx        | 42789       |     | Facility           | 3     | Other Cardiac Dysrhythmias                |                            |             |     |                            | TEDN   | 134    |
| 248         | -38             | 09/24/2013                     |                | Px        | 93005       |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                            |             |     |                            | TEDN   | 134    |
| 249         | -31             | 10/01/2013                     |                | Dx        | 71534       |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                            |             |     |                            | TEDN   | 136    |
| 250         | -31             | 10/01/2013                     |                | Px        | 25310       |     | Ortho              | 1     | Tdn Trnsplj/Tr Flxr/Xtnsr F/Arm&/Wrst 1 E |                            |             |     |                            | TEDN   | 136    |
| 251         | -31             | 10/01/2013                     |                | Px        | 25447       |     | Ortho              | 1     | Arthrp Interpos Intercarpal/Metacarpal Jo |                            |             |     |                            | TEDN   | 137    |
| 252         | -31             | 10/01/2013                     |                | Dx        | 71694       |     | Grppract           | 1     | Uns Arthopathy Hand                       |                            |             |     |                            | TEDN   | 138    |
| 253         | -31             | 10/01/2013                     |                | Dx        | 412         |     | Grppract           | 2     | Old Myocardial Infarction                 |                            |             |     |                            | TEDN   | 138    |
| 254         | -31             | 10/01/2013                     |                | Dx        | 33818       |     | Grppract           | 3     | Other Acute Postoperative Pain            |                            |             |     |                            | TEDN   | 138    |
| 255         | -31             | 10/01/2013                     |                | Px        | 01830       |     | Grppract           | 1     | Anes Arthrs/Endscpy Dstl Radius Ulna/Wris |                            |             |     |                            | TEDN   | 138    |
| 256         | -31             | 10/01/2013                     |                | Px        | 64417       |     | Grppract           | 1     | Injection Anesthetic Agent Axillary Nerve |                            |             |     |                            | TEDN   | 139    |
| 257         | -31             | 10/01/2013                     |                | Dx        | 71594       |     | Facility           | 1     | Osteoarthritis Unsp Hand                  |                            |             |     |                            | TEDN   | 140    |
| 258         | -31             | 10/01/2013                     |                | Px        | 25310       |     | Facility           | 1     | Tdn Trnsplj/Tr Flxr/Xtnsr F/Arm&/Wrst 1 E |                            |             |     |                            | TEDN   | 140    |



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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 259         | -31             | 10/01/2013                     |                | Px        | 25447       |      | Facility           | 1     | Arthrp Interpos Intercarpal/Metacarpal Jo |                        |             |     |                  | TEDN   | 141    |
| 260         | -31             | 10/01/2013                     |                | Rx        | 00378611201 |      |                    |       |                                           | Oxycodone Hcl          | 4           | 65  | Tablet           | PDTS   | 135    |
| 261         | -30             | 10/02/2013                     |                | Rx        | 67877017030 |      |                    |       |                                           | Ondansetron Hcl        | 10          | 10  | Tablet           | PDTS   | 142    |
| 262         | -19             | 10/13/2013                     |                | Dx        | 78909       |      | Ambul              | 1     | Abdominal Pain Other Site                 |                        |             |     |                  | TEDN   | 146    |
| 263         | -19             | 10/13/2013                     |                | Dx        | 78652       |      | Ambul              | 2     | Painful Respiration                       |                        |             |     |                  | TEDN   | 146    |
| 264         | -19             | 10/13/2013                     |                | Dx        | 5362        |      | Ambul              | 3     | Persistent Vomiting                       |                        |             |     |                  | TEDN   | 146    |
| 265         | -19             | 10/13/2013                     |                | Px        | A0425       |      | Ambul              | 1     | Ground Mileage                            |                        |             |     |                  | TEDN   | 146    |
| 266         | -19             | 10/13/2013                     |                | Px        | A0429       |      | Ambul              | 1     | Bls-Emergency                             |                        |             |     |                  | TEDN   | 147    |
| 267         | -19             | 10/13/2013                     |                | Dx        | 42731       |      | Grpract            | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 148    |
| 268         | -19             | 10/13/2013                     |                | Dx        | 72888       |      | Grpract            | 2     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 148    |
| 269         | -19             | 10/13/2013                     |                | Px        | 36556       |      | Grpract            | 1     | Insj Non-Tunneled Central Venous Cath Age |                        |             |     |                  | TEDN   | 148    |
| 270         | -19             | 10/13/2013                     |                | Px        | 99291       |      | Grpract            | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 149    |
| 271         | -19             | 10/13/2013                     |                | Px        | 99292       |      | Grpract            | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 150    |
| 272         | -19             | 10/13/2013                     |                | Px        | 71010       |      | Grpract            | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 151    |
| 273         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 42731       |      |                    | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 153    |
| 274         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 72888       |      |                    | 2     | Rhabdomyolysis                            |                        |             |     |                  | TEDI   | 153    |
| 275         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 78550       |      |                    | 3     | Shock Unspecified                         |                        |             |     |                  | TEDI   | 153    |
| 276         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 3572        |      |                    | 4     | Polyneuropathy In Diabetes                |                        |             |     |                  | TEDI   | 153    |
| 277         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 27651       |      |                    | 5     | Dehydration                               |                        |             |     |                  | TEDI   | 153    |
| 278         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 2752        |      |                    | 6     | Disorders Magnesium Metabolism            |                        |             |     |                  | TEDI   | 153    |
| 279         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 25060       |      |                    | 7     | Diabetes Neuro Manif Type II              |                        |             |     |                  | TEDI   | 153    |
| 280         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 5589        |      |                    | 8     | Oth Noninfectious Gastroenteritis         |                        |             |     |                  | TEDI   | 153    |
| 281         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 41401       |      |                    | 9     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDI   | 153    |
| 282         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 4019        |      |                    | 10    | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 153    |
| 283         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 78791       |      |                    | 11    | Diarrhea                                  |                        |             |     |                  | TEDI   | 153    |
| 284         | -19             | 10/13/2013                     | 10/18/2013     | Dx        | 2724        |      |                    | 12    | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDI   | 153    |
| 285         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 3893        |      |                    | 1     | Venous Cath Other Spec                    |                        |             |     |                  | TEDI   | 153    |
| 286         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9383        |      |                    | 2     | Occupational Therapy                      |                        |             |     |                  | TEDI   | 153    |
| 287         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9919        |      |                    | 3     | Injection Of Anticoagulant                |                        |             |     |                  | TEDI   | 153    |
| 288         | -19             | 10/13/2013                     | 10/18/2013     | Px        | 9952        |      |                    | 4     | Influenza Vaccination                     |                        |             |     |                  | TEDI   | 153    |
| 289         | -19             | 10/13/2013                     |                | Dx        | 42731       | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 143    |
| 290         | -19             | 10/13/2013                     |                | Dx        | 4293        | Inpt | Cardvasc           | 2     | Cardiomegaly                              |                        |             |     |                  | TEDN   | 143    |
| 291         | -19             | 10/13/2013                     |                | Dx        | 72888       | Inpt | Cardvasc           | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 143    |
| 292         | -19             | 10/13/2013                     |                | Px        | 93010       | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 143    |
| 293         | -19             | 10/13/2013                     |                | Px        | 93010       | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 144    |
| 294         | -19             | 10/13/2013                     |                | Dx        | 78650       | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 145    |
| 295         | -19             | 10/13/2013                     |                | Dx        | 42731       | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 145    |
| 296         | -19             | 10/13/2013                     |                | Dx        | 72888       | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 145    |
| 297         | -19             | 10/13/2013                     |                | Dx        | 78550       | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 145    |
| 298         | -19             | 10/13/2013                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 145    |
| 300         | -18             | 10/14/2013                     |                | Dx        | 42731       | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 154    |
| 301         | -18             | 10/14/2013                     |                | Dx        | 25002       | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 154    |
| 302         | -18             | 10/14/2013                     |                | Dx        | 41401       | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 154    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 303         | -18             | 10/14/2013                     |                | Dx        | 4011  | Inpt | Cardvasc           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 154    |
| 304         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 154    |
| 305         | -18             | 10/14/2013                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 155    |
| 306         | -18             | 10/14/2013                     |                | Dx        | 78650 | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 156    |
| 307         | -18             | 10/14/2013                     |                | Dx        | 42731 | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 156    |
| 308         | -18             | 10/14/2013                     |                | Dx        | 72888 | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 156    |
| 309         | -18             | 10/14/2013                     |                | Dx        | 78550 | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 156    |
| 310         | -18             | 10/14/2013                     |                | Px        | 99233 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 156    |
| 311         | -18             | 10/14/2013                     |                | Dx        | 28860 | Inpt | Intmed             | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 157    |
| 312         | -18             | 10/14/2013                     |                | Px        | 99223 | Inpt | Intmed             | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                  | TEDN   | 157    |
| 313         | -18             | 10/14/2013                     |                | Dx        | 7905  | Inpt | Radio              | 1     | Oth Abnormal Serum Enzyme Levels          |                        |             |     |                  | TEDN   | 158    |
| 314         | -18             | 10/14/2013                     |                | Px        | 76705 | Inpt | Radio              | 1     | Ultrasound Abdominal Real Time W/Image Li |                        |             |     |                  | TEDN   | 158    |
| 315         | -18             | 10/14/2013                     |                | Dx        | 0389  | Inpt | Grppract           | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 159    |
| 316         | -18             | 10/14/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 159    |
| 317         | -18             | 10/14/2013                     |                | Dx        | 99592 | Inpt | Grppract           | 3     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 159    |
| 318         | -18             | 10/14/2013                     |                | Dx        | 4271  | Inpt | Grppract           | 4     | Paroxysmal Ventricular Tachycardia        |                        |             |     |                  | TEDN   | 159    |
| 319         | -18             | 10/14/2013                     |                | Px        | 99292 | Inpt | Grppract           | 1     | Critical Care Ill/Injured Patient Addl 30 |                        |             |     |                  | TEDN   | 159    |
| 320         | -18             | 10/14/2013                     |                | Px        | 99291 | Inpt | Grppract           | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                  | TEDN   | 160    |
| 321         | -18             | 10/14/2013                     |                | Px        | 71260 | Inpt | Grppract           | 1     | Ct Thorax W/Contrast Material             |                        |             |     |                  | TEDN   | 161    |
| 322         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 162    |
| 323         | -18             | 10/14/2013                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 163    |
| 324         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 164    |
| 325         | -17             | 10/15/2013                     |                | Dx        | 25002 | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 164    |
| 326         | -17             | 10/15/2013                     |                | Dx        | 41401 | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 164    |
| 327         | -17             | 10/15/2013                     |                | Dx        | 4011  | Inpt | Cardvasc           | 4     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 164    |
| 328         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 164    |
| 329         | -17             | 10/15/2013                     |                | Dx        | 78650 | Inpt | Fp                 | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 165    |
| 330         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Fp                 | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 165    |
| 331         | -17             | 10/15/2013                     |                | Dx        | 72888 | Inpt | Fp                 | 3     | Rhabdomyolysis                            |                        |             |     |                  | TEDN   | 165    |
| 332         | -17             | 10/15/2013                     |                | Dx        | 78550 | Inpt | Fp                 | 4     | Shock Unspecified                         |                        |             |     |                  | TEDN   | 165    |
| 333         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 165    |
| 334         | -17             | 10/15/2013                     |                | Dx        | 28860 | Inpt | Intmed             | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 166    |
| 335         | -17             | 10/15/2013                     |                | Px        | 99233 | Inpt | Intmed             | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 166    |
| 336         | -17             | 10/15/2013                     |                | Dx        | 0389  | Inpt | Grppract           | 1     | Uns Septicemia                            |                        |             |     |                  | TEDN   | 167    |
| 337         | -17             | 10/15/2013                     |                | Dx        | 42731 | Inpt | Grppract           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 167    |
| 338         | -17             | 10/15/2013                     |                | Dx        | 99592 | Inpt | Grppract           | 3     | Severe Sepsis                             |                        |             |     |                  | TEDN   | 167    |
| 339         | -17             | 10/15/2013                     |                | Dx        | 4271  | Inpt | Grppract           | 4     | Paroxysmal Ventricular Tachycardia        |                        |             |     |                  | TEDN   | 167    |
| 340         | -17             | 10/15/2013                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 167    |
| 341         | -17             | 10/15/2013                     |                | Px        | 99231 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 168    |
| 342         | -17             | 10/15/2013                     |                | Px        | 99231 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 169    |
| 343         | -16             | 10/16/2013                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 170    |
| 344         | -16             | 10/16/2013                     |                | Dx        | 25002 | Inpt | Cardvasc           | 2     | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                  | TEDN   | 170    |
| 345         | -16             | 10/16/2013                     |                | Dx        | 41401 | Inpt | Cardvasc           | 3     | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDN   | 170    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|------|--------------------|--------|-------------------------------------------|------------------------|-------------|-----|-----------------------------|--------|--------|
| 346         | -16             | 10/16/2013                     |                | Dx        | 4011             | Inpt | Cardvasc           | 4      | Benign Essential Hypertension             |                        |             |     |                             | TEDN   | 170    |
| 347         | -16             | 10/16/2013                     |                | Px        | 99232            | Inpt | Cardvasc           | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 170    |
| 348         | -16             | 10/16/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 171    |
| 349         | -16             | 10/16/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 171    |
| 350         | -16             | 10/16/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 171    |
| 351         | -16             | 10/16/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 171    |
| 352         | -16             | 10/16/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 171    |
| 353         | -16             | 10/16/2013                     |                | Dx        | 28860            | Inpt | Intmed             | 1      | Leukocytosis Unspecified                  |                        |             |     |                             | TEDN   | 172    |
| 354         | -16             | 10/16/2013                     |                | Px        | 99233            | Inpt | Intmed             | 1      | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                             | TEDN   | 172    |
| 355         | -15             | 10/17/2013                     |                | Dx        | 42731            | Inpt | Cardvasc           | 1      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 173    |
| 356         | -15             | 10/17/2013                     |                | Dx        | 25002            | Inpt | Cardvasc           | 2      | Diabetes Uncomp Type II Uncontrd          |                        |             |     |                             | TEDN   | 173    |
| 357         | -15             | 10/17/2013                     |                | Dx        | 41401            | Inpt | Cardvasc           | 3      | Atheroscler Native Coronary Art           |                        |             |     |                             | TEDN   | 173    |
| 358         | -15             | 10/17/2013                     |                | Dx        | 4011             | Inpt | Cardvasc           | 4      | Benign Essential Hypertension             |                        |             |     |                             | TEDN   | 173    |
| 359         | -15             | 10/17/2013                     |                | Px        | 99232            | Inpt | Cardvasc           | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 173    |
| 360         | -15             | 10/17/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 174    |
| 361         | -15             | 10/17/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 174    |
| 362         | -15             | 10/17/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 174    |
| 363         | -15             | 10/17/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 174    |
| 364         | -15             | 10/17/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 174    |
| 365         | -15             | 10/17/2013                     |                | Dx        | 28860            | Inpt | Intmed             | 1      | Leukocytosis Unspecified                  |                        |             |     |                             | TEDN   | 175    |
| 366         | -15             | 10/17/2013                     |                | Px        | 99232            | Inpt | Intmed             | 1      | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                             | TEDN   | 175    |
| 367         | -15             | 10/17/2013                     |                | Dx        | 78605            | Inpt | Radio              | 1      | Shortness Breath                          |                        |             |     |                             | TEDN   | 176    |
| 368         | -15             | 10/17/2013                     |                | Dx        | 78060            | Inpt | Radio              | 2      | Fever Unspecified                         |                        |             |     |                             | TEDN   | 176    |
| 369         | -15             | 10/17/2013                     |                | Px        | 71020            | Inpt | Radio              | 1      | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                             | TEDN   | 176    |
| 375         | -14             | 10/18/2013                     |                | Dx        | 78650            | Inpt | Fp                 | 1      | Unspec Chest Pain                         |                        |             |     |                             | TEDN   | 177    |
| 376         | -14             | 10/18/2013                     |                | Dx        | 42731            | Inpt | Fp                 | 2      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 177    |
| 377         | -14             | 10/18/2013                     |                | Dx        | 72888            | Inpt | Fp                 | 3      | Rhabdomyolysis                            |                        |             |     |                             | TEDN   | 177    |
| 378         | -14             | 10/18/2013                     |                | Dx        | 78550            | Inpt | Fp                 | 4      | Shock Unspecified                         |                        |             |     |                             | TEDN   | 177    |
| 379         | -14             | 10/18/2013                     |                | Px        | 99231            | Inpt | Fp                 | 1      | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                             | TEDN   | 177    |
| 370         | -14             | 10/18/2013                     |                | Dx        | 7812             |      | Ambul              | 1      | Abnormality Of Gait                       |                        |             |     |                             | TEDN   | 178    |
| 371         | -14             | 10/18/2013                     |                | Dx        | V4984            |      | Ambul              | 2      | Bed Confinement Status                    |                        |             |     |                             | TEDN   | 178    |
| 372         | -14             | 10/18/2013                     |                | Dx        | 7993             |      | Ambul              | 3      | Debility Unspecified                      |                        |             |     |                             | TEDN   | 178    |
| 373         | -14             | 10/18/2013                     |                | Px        | A0425            |      | Ambul              | 1      | Ground Mileage                            |                        |             |     |                             | TEDN   | 178    |
| 374         | -14             | 10/18/2013                     |                | Px        | A0428            |      | Ambul              | 1      | Bls                                       |                        |             |     |                             | TEDN   | 179    |
| 380         | -9              | 10/23/2013                     |                | Dx        | 7295             |      | Fp                 | 1      | Pain In Limb                              |                        |             |     |                             | TEDN   | 180    |
| 381         | -9              | 10/23/2013                     |                | Px        | 99309            |      | Fp                 | 1      | Sbsq Nursing Facil Care/Day New Problem 2 |                        |             |     |                             | TEDN   | 180    |
| 382         | 0               | 11/01/2013                     |                | Rx        | 00378668910      |      |                    |        |                                           | Pantoprazole Sodium    | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 181    |
| 383         | 0               | 11/01/2013                     |                | Rx        | 45963053830      |      |                    |        |                                           | Ondansetron Hcl        | 8           | 30  | Tablet                      | PDTS   | 182    |
| 384         | 0               | 11/01/2013                     |                | Rx        | 68382006401      |      |                    |        |                                           | Warfarin Sodium        | 30          | 30  | Tablet                      | PDTS   | 183    |
| 385         | 0               | 11/01/2013                     |                | Rx        | 64980015701      |      |                    |        |                                           | Vitamin D2             | 28          | 4   | Capsule (Hard, Soft, Etc.)  | PDTS   | 184    |
| 386         | 0               | 11/01/2013                     |                | Rx        | 00310075290      |      |                    |        |                                           | Crestor                | 30          | 30  | Tablet                      | PDTS   | 185    |
| 387         | 0               | 11/01/2013                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |      |                    |        |                                           | INDEX STUDY DRUG       | 30          |     | INITIAL FILL                | PDTS   | 186    |
| 388         | 3               | 11/04/2013                     |                | Dx        | 42731            |      | Grppract           | 1      | Atrial Fibrillation                       |                        |             |     |                             | TEDN   | 187    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|---------------------------|-------------|-----|-----------------------------|--------|--------|
| 389         | 3               | 11/04/2013                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                           |             |     |                             | TEDN   | 187    |
| 390         | 5               | 11/06/2013                     |                | Dx        | 71534            |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 188    |
| 391         | 5               | 11/06/2013                     |                | Px        | 73130            |     | Ortho              | 1     | Radex Hand Minimum 3 Views                |                           |             |     |                             | TEDN   | 188    |
| 392         | 5               | 11/06/2013                     |                | Dx        | 7812             |     | Grppract           | 1     | Abnormality Of Gait                       |                           |             |     |                             | TEDN   | 189    |
| 393         | 5               | 11/06/2013                     |                | Px        | 97001            |     | Grppract           | 1     | Physical Therapy Evaluation               |                           |             |     |                             | TEDN   | 189    |
| 394         | 5               | 11/06/2013                     |                | Px        | 97110            |     | Grppract           | 1     | Therapeutic Px 1/> Areas Each 15 Min Exer |                           |             |     |                             | TEDN   | 190    |
| 395         | 5               | 11/06/2013                     |                | Px        | 97530            |     | Grppract           | 1     | Ther Actv Dir Pt Contact By Provider Each |                           |             |     |                             | TEDN   | 191    |
| 396         | 18              | 11/19/2013                     |                | Rx        | 55111012705      |     |                    |       |                                           | Ciprofloxacin Hcl         | 7           | 14  | Tablet                      | PDTS   | 192    |
| 397         | 20              | 11/21/2013                     |                | Dx        | 71534            |     | Ortho              | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 196    |
| 398         | 20              | 11/21/2013                     |                | Px        | 73110            |     | Ortho              | 1     | Radex Wrist Complete Minimum 3 Views      |                           |             |     |                             | TEDN   | 196    |
| 399         | 20              | 11/21/2013                     |                | Dx        | 71534            |     | Grppract           | 1     | Osteoarthritis Local Hand                 |                           |             |     |                             | TEDN   | 197    |
| 400         | 20              | 11/21/2013                     |                | Px        | L3908            |     | Grppract           | 1     | Wrist Cock-Up Non-Molded                  |                           |             |     |                             | TEDN   | 197    |
| 401         | 20              | 11/21/2013                     |                | Rx        | 59762444002      |     |                    |       |                                           | Methylprednisolone        | 6           | 21  | Tablet, Dose Pack           | PDTS   | 193    |
| 402         | 20              | 11/21/2013                     |                | Rx        | 00071101468      |     |                    |       |                                           | Lyrica                    | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 194    |
| 403         | 20              | 11/21/2013                     |                | Rx        | 00406051205      |     |                    |       |                                           | Oxycodone-Acetaminophen   | 3           | 40  | Tablet                      | PDTS   | 195    |
| 404         | 29              | 11/30/2013                     |                | Rx        | 00378668910      |     |                    |       |                                           | Pantoprazole Sodium       | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 198    |
| 405         | 29              | 11/30/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG          | 30          |     | REFILL                      | PDTS   | 199    |
| 406         | 29              | 11/30/2013                     |                | Rx        | 68382006401      |     |                    |       |                                           | Warfarin Sodium           | 30          | 30  | Tablet                      | PDTS   | 200    |
| 407         | 29              | 11/30/2013                     |                | Rx        | 00310075290      |     |                    |       |                                           | Crestor                   | 30          | 30  | Tablet                      | PDTS   | 201    |
| 408         | 46              | 12/17/2013                     |                | Dx        | 41401            |     | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                           |             |     |                             | TEDN   | 204    |
| 409         | 46              | 12/17/2013                     |                | Dx        | 4011             |     | Cardvasc           | 2     | Benign Essential Hypertension             |                           |             |     |                             | TEDN   | 204    |
| 410         | 46              | 12/17/2013                     |                | Dx        | 2722             |     | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                           |             |     |                             | TEDN   | 204    |
| 411         | 46              | 12/17/2013                     |                | Dx        | 25000            |     | Cardvasc           | 4     | Diabetes Uncompl Type Ii                  |                           |             |     |                             | TEDN   | 204    |
| 412         | 46              | 12/17/2013                     |                | Px        | 99214            |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                             | TEDN   | 204    |
| 413         | 46              | 12/17/2013                     |                | Rx        | 0                |     |                    |       |                                           | Compounded Medication     | 6           | 360 |                             | PDTS   | 202    |
| 414         | 46              | 12/17/2013                     |                | Rx        | 00603646832      |     |                    |       |                                           | Zolpidem Tartrate         | 30          | 30  | Tablet                      | PDTS   | 203    |
| 415         | 52              | 12/23/2013                     |                | Dx        | 25060            |     | Podia              | 1     | Diabetes Neuro Manif Type Ii              |                           |             |     |                             | TEDN   | 205    |
| 416         | 52              | 12/23/2013                     |                | Dx        | 3560             |     | Podia              | 2     | Hereditary Peripheral Neuropathy          |                           |             |     |                             | TEDN   | 205    |
| 417         | 52              | 12/23/2013                     |                | Dx        | 7030             |     | Podia              | 3     | Ingrowing Nail                            |                           |             |     |                             | TEDN   | 205    |
| 418         | 52              | 12/23/2013                     |                | Dx        | 1101             |     | Podia              | 4     | Dermatophytosis Nail                      |                           |             |     |                             | TEDN   | 205    |
| 419         | 52              | 12/23/2013                     |                | Dx        | 73037            |     | Podia              | 5     | Periostitis Ankle/Foot                    |                           |             |     |                             | TEDN   | 205    |
| 420         | 52              | 12/23/2013                     |                | Px        | 11721            |     | Podia              | 1     | Debridement Nail Any Method 6/>           |                           |             |     |                             | TEDN   | 205    |
| 421         | 55              | 12/26/2013                     |                | Dx        | 92411            |     | Ortho              | 1     | Contusion Of Knee                         |                           |             |     |                             | TEDN   | 207    |
| 422         | 55              | 12/26/2013                     |                | Px        | 99214            |     | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                           |             |     |                             | TEDN   | 207    |
| 423         | 55              | 12/26/2013                     |                | Dx        | 71946            |     | Grppract           | 1     | Pain In Joint Lower Leg                   |                           |             |     |                             | TEDN   | 208    |
| 424         | 55              | 12/26/2013                     |                | Dx        | V4365            |     | Grppract           | 2     | Knee Joint Replacement                    |                           |             |     |                             | TEDN   | 208    |
| 425         | 55              | 12/26/2013                     |                | Px        | 73562            |     | Grppract           | 1     | Radiologic Examination Knee 3 Views       |                           |             |     |                             | TEDN   | 208    |
| 426         | 55              | 12/26/2013                     |                | Rx        | 00603389028      |     |                    |       |                                           | Hydrocodone-Acetaminophen | 10          | 40  | Tablet                      | PDTS   | 206    |
| 427         | 59              | 12/30/2013                     |                | Rx        | 00071101468      |     |                    |       |                                           | Lyrica                    | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 209    |
| 428         | 61              | 01/01/2014                     |                | Dx        | 7245             |     | Pa                 | 1     | Backache Unspecified                      |                           |             |     |                             | TEDN   | 214    |
| 429         | 61              | 01/01/2014                     |                | Px        | 99283            |     | Pa                 | 1     | Emergency Department Visit Moderate Sever |                           |             |     |                             | TEDN   | 214    |
| 430         | 61              | 01/01/2014                     |                | Dx        | 33819            |     | Facility           | 1     | Other Acute Pain                          |                           |             |     |                             | TEDN   | 215    |
| 431         | 61              | 01/01/2014                     |                | Dx        | 7245             |     | Facility           | 2     | Backache Unspecified                      |                           |             |     |                             | TEDN   | 215    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|-----------------------------|--------|--------|
| 432         | 61              | 01/01/2014                     |                | Dx        | 25000       |     | Facility           | 3     | Diabetes Uncompl Type II                  |                            |             |     |                             | TEDN   | 215    |
| 433         | 61              | 01/01/2014                     |                | Dx        | 4019        |     | Facility           | 4     | Unspecified Essential Hypertension        |                            |             |     |                             | TEDN   | 215    |
| 434         | 61              | 01/01/2014                     |                | Dx        | 41400       |     | Facility           | 5     | Coronary Atheroscler Uns Vessel           |                            |             |     |                             | TEDN   | 215    |
| 435         | 61              | 01/01/2014                     |                | Dx        | 412         |     | Facility           | 6     | Old Myocardial Infarction                 |                            |             |     |                             | TEDN   | 215    |
| 436         | 61              | 01/01/2014                     |                | Dx        | 42731       |     | Facility           | 7     | Atrial Fibrillation                       |                            |             |     |                             | TEDN   | 215    |
| 437         | 61              | 01/01/2014                     |                | Px        | 99070       |     | Facility           | 1     | Supplies&materials Prv By Phys >&above    |                            |             |     |                             | TEDN   | 215    |
| 438         | 61              | 01/01/2014                     |                | Px        | 99281       |     | Facility           | 1     | Emergency Department Visit Limited/Minor  |                            |             |     |                             | TEDN   | 216    |
| 439         | 61              | 01/01/2014                     |                | Px        | 99283       |     | Facility           | 1     | Emergency Department Visit Moderate Sever |                            |             |     |                             | TEDN   | 217    |
| 440         | 61              | 01/01/2014                     |                | Px        | C9399       |     | Facility           | 1     | Unclassified Drugs Or Biolog              |                            |             |     |                             | TEDN   | 218    |
| 441         | 61              | 01/01/2014                     |                | Rx        | 00054001925 |     |                    |       |                                           | Prednisone                 | 4           | 4   | Tablet                      | PDTS   | 210    |
| 442         | 61              | 01/01/2014                     |                | Rx        | 00603389028 |     |                    |       |                                           | Hydrocodone-Acetaminophen  | 4           | 14  | Tablet                      | PDTS   | 211    |
| 443         | 61              | 01/01/2014                     |                | Rx        | 59746021110 |     |                    |       |                                           | Cyclobenzaprine Hcl        | 6           | 20  | Tablet                      | PDTS   | 212    |
| 444         | 61              | 01/01/2014                     |                | Rx        | 45963053830 |     |                    |       |                                           | Ondansetron Hcl            | 3           | 10  | Tablet                      | PDTS   | 213    |
| 445         | 62              | 01/02/2014                     |                | Rx        | 00378668910 |     |                    |       |                                           | Pantoprazole Sodium        | 30          | 60  | Tablet, DR (Enteric Coated) | PDTS   | 219    |
| 446         | 62              | 01/02/2014                     |                | Rx        | 00310075290 |     |                    |       |                                           | Crestor                    | 30          | 30  | Tablet                      | PDTS   | 220    |
| 447         | 69              | 01/09/2014                     |                | Dx        | 42769       |     | Facility           | 1     | Oth Premature Beats                       |                            |             |     |                             | TEDN   | 221    |
| 448         | 69              | 01/09/2014                     |                | Dx        | 42761       |     | Facility           | 2     | Supraventricular Premature Beats          |                            |             |     |                             | TEDN   | 221    |
| 449         | 69              | 01/09/2014                     |                | Dx        | 42731       |     | Facility           | 3     | Atrial Fibrillation                       |                            |             |     |                             | TEDN   | 221    |
| 450         | 69              | 01/09/2014                     |                | Px        | 93225       |     | Facility           | 1     | Xtrnl Ecg < 48 Hr Recording               |                            |             |     |                             | TEDN   | 221    |
| 451         | 69              | 01/09/2014                     |                | Px        | 93226       |     | Facility           | 1     | External Ecg Scanning Analysis Report     |                            |             |     |                             | TEDN   | 222    |
| 452         | 76              | 01/16/2014                     |                | Dx        | 41401       |     | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                            |             |     |                             | TEDN   | 223    |
| 453         | 76              | 01/16/2014                     |                | Dx        | 4011        |     | Cardvasc           | 2     | Benign Essential Hypertension             |                            |             |     |                             | TEDN   | 223    |
| 454         | 76              | 01/16/2014                     |                | Dx        | 2722        |     | Cardvasc           | 3     | Mixed Hyperlipidemia                      |                            |             |     |                             | TEDN   | 223    |
| 455         | 76              | 01/16/2014                     |                | Dx        | 25000       |     | Cardvasc           | 4     | Diabetes Uncompl Type II                  |                            |             |     |                             | TEDN   | 223    |
| 456         | 76              | 01/16/2014                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                             | TEDN   | 223    |
| 457         | 87              | 01/27/2014                     |                | Dx        | 7295        |     | Grpract            | 1     | Pain In Limb                              |                            |             |     |                             | TEDN   | 225    |
| 458         | 87              | 01/27/2014                     |                | Px        | 99213       |     | Grpract            | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                             | TEDN   | 225    |
| 459         | 87              | 01/27/2014                     |                | Rx        | 57664037718 |     |                    |       |                                           | Tramadol Hcl               | 12          | 50  | Tablet                      | PDTS   | 224    |
| 460         | 93              | 02/02/2014                     |                | Rx        | 00071101468 |     |                    |       |                                           | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 226    |
| 461         | 101             | 02/10/2014                     |                | Rx        | 54569214000 |     |                    |       |                                           | Nitrostat                  | 30          | 100 | Tablet, Sublingual          | PDTS   | 227    |
| 462         | 101             | 02/10/2014                     |                | Rx        | 63653117105 |     |                    |       |                                           | Plavix                     | 90          | 90  | Tablet                      | PDTS   | 228    |
| 463         | 101             | 02/10/2014                     |                | Rx        | 53746025310 |     |                    |       |                                           | Ranitidine Hcl             | 90          | 360 | Tablet                      | PDTS   | 229    |
| 464         | 101             | 02/10/2014                     |                | Rx        | 49884040401 |     |                    |       |                                           | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr             | PDTS   | 230    |
| 465         | 101             | 02/10/2014                     |                | Rx        | 00078037905 |     |                    |       |                                           | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.)  | PDTS   | 231    |
| 466         | 101             | 02/10/2014                     |                | Rx        | 00904584940 |     |                    |       |                                           | Metformin Hcl              | 90          | 90  | Tablet                      | PDTS   | 232    |
| 467         | 102             | 02/11/2014                     |                | Rx        | 00603646832 |     |                    |       |                                           | Zolpidem Tartrate          | 30          | 30  | Tablet                      | PDTS   | 233    |
| 468         | 102             | 02/11/2014                     |                | Rx        | 00008084181 |     |                    |       |                                           | Protonix                   | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 234    |
| 469         | 102             | 02/11/2014                     |                | Rx        | 00310075290 |     |                    |       |                                           | Crestor                    | 90          | 90  | Tablet                      | PDTS   | 235    |
| 470         | 102             | 02/11/2014                     |                | Rx        | 00009519103 |     |                    |       |                                           | Detrol La                  | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 236    |
| 471         | 125             | 03/06/2014                     |                | Dx        | 71946       |     | Ortho              | 1     | Pain In Joint Lower Leg                   |                            |             |     |                             | TEDN   | 239    |
| 472         | 125             | 03/06/2014                     |                | Px        | 99214       |     | Ortho              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                             | TEDN   | 239    |
| 473         | 125             | 03/06/2014                     |                | Rx        | 66993089845 |     |                    |       |                                           | Clotrimazole-Betamethasone | 4           | 45  | Cream (Grams)               | PDTS   | 237    |
| 474         | 125             | 03/06/2014                     |                | Rx        | 00093015010 |     |                    |       |                                           | Acetaminophen-Codeine      | 15          | 90  | Tablet                      | PDTS   | 238    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------|--------|--------|
| 475         | 127             | 03/08/2014                     |                | Rx        | 00071101468 |      |                    |       |                                           | Lyrica                 | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 240    |
| 476         | 150             | 03/31/2014                     |                | Dx        | 25060       |      | Podia              | 1     | Diabetes Neuro Manif Type Ii              |                        |             |     |                            | TEDN   | 241    |
| 477         | 150             | 03/31/2014                     |                | Dx        | 3560        |      | Podia              | 2     | Hereditary Peripheral Neuropathy          |                        |             |     |                            | TEDN   | 241    |
| 478         | 150             | 03/31/2014                     |                | Dx        | 7030        |      | Podia              | 3     | Ingrowing Nail                            |                        |             |     |                            | TEDN   | 241    |
| 479         | 150             | 03/31/2014                     |                | Dx        | 1101        |      | Podia              | 4     | Dermatophytosis Nail                      |                        |             |     |                            | TEDN   | 241    |
| 480         | 150             | 03/31/2014                     |                | Dx        | 73037       |      | Podia              | 5     | Periostitis Ankle/Foot                    |                        |             |     |                            | TEDN   | 241    |
| 481         | 150             | 03/31/2014                     |                | Dx        | 3556        |      | Podia              | 6     | Lesion Plantar Nerve                      |                        |             |     |                            | TEDN   | 241    |
| 482         | 150             | 03/31/2014                     |                | Dx        | 73399       |      | Podia              | 7     | Other Disorders Bone/Cartilage            |                        |             |     |                            | TEDN   | 241    |
| 483         | 150             | 03/31/2014                     |                | Px        | 11721       |      | Podia              | 1     | Debridement Nail Any Method 6/>           |                        |             |     |                            | TEDN   | 241    |
| 484         | 150             | 03/31/2014                     |                | Px        | 99212       |      | Podia              | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                            | TEDN   | 242    |
| 485         | 150             | 03/31/2014                     |                | Dx        | 7823        |      | Grpract            | 1     | Edema                                     |                        |             |     |                            | TEDN   | 243    |
| 486         | 150             | 03/31/2014                     |                | Dx        | 7822        |      | Grpract            | 2     | Localized Superficial Swelling            |                        |             |     |                            | TEDN   | 243    |
| 487         | 150             | 03/31/2014                     |                | Px        | 73721       |      | Grpract            | 1     | Mri Any Jt Lower Extrem W/O Contrast Matr |                        |             |     |                            | TEDN   | 243    |
| 488         | 160             | 04/10/2014                     |                | Dx        | 7245        |      | Fp                 | 1     | Backache Unspecified                      |                        |             |     |                            | TEDN   | 244    |
| 489         | 160             | 04/10/2014                     |                | Dx        | 3572        |      | Fp                 | 2     | Polyneuropathy In Diabetes                |                        |             |     |                            | TEDN   | 244    |
| 490         | 160             | 04/10/2014                     |                | Dx        | 25000       |      | Fp                 | 3     | Diabetes Uncompl Type Ii                  |                        |             |     |                            | TEDN   | 244    |
| 491         | 160             | 04/10/2014                     |                | Dx        | 8472        |      | Fp                 | 4     | Sprain/Strain Lumbar Region               |                        |             |     |                            | TEDN   | 244    |
| 492         | 160             | 04/10/2014                     |                | Dx        | 5950        |      | Fp                 | 5     | Acute Cystitis                            |                        |             |     |                            | TEDN   | 244    |
| 493         | 160             | 04/10/2014                     |                | Px        | 81002       |      | Fp                 | 1     | Urnl's Dip Stick/Tablet Rgnt Non-Auto W/O |                        |             |     |                            | TEDN   | 244    |
| 494         | 160             | 04/10/2014                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 245    |
| 495         | 164             | 04/14/2014                     |                | Rx        | 00071101468 |      |                    |       |                                           | Lyrica                 | 30          | 60  | Capsule (Hard, Soft, Etc.) | PDTS   | 246    |
| 496         | 165             | 04/15/2014                     |                | Rx        | 57664037718 |      |                    |       |                                           | Tramadol Hcl           | 12          | 50  | Tablet                     | PDTS   | 247    |
| 497         | 178             | 04/28/2014                     |                | Dx        | 25000       |      | Fp                 | 1     | Diabetes Uncompl Type Ii                  |                        |             |     |                            | TEDN   | 250    |
| 498         | 178             | 04/28/2014                     |                | Dx        | 460         |      | Fp                 | 2     | Acute Nasopharyngitis                     |                        |             |     |                            | TEDN   | 250    |
| 499         | 178             | 04/28/2014                     |                | Px        | 99213       |      | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                            | TEDN   | 250    |
| 500         | 178             | 04/28/2014                     |                | Rx        | 57664018534 |      |                    |       |                                           | Promethazine-Codeine   | 18          | 180 | Syrup                      | PDTS   | 248    |
| 501         | 178             | 04/28/2014                     |                | Rx        | 00781506101 |      |                    |       |                                           | Amoxicillin            | 10          | 20  | Tablet                     | PDTS   | 249    |
| 502         | 193             | 05/13/2014                     |                | Dx        | 51881       |      | Gp                 | 1     | Respiratory Failure                       |                        |             |     |                            | TEDN   | 251    |
| 503         | 193             | 05/13/2014                     |                | Dx        | 0389        |      | Gp                 | 2     | Un's Septicemia                           |                        |             |     |                            | TEDN   | 251    |
| 504         | 193             | 05/13/2014                     |                | Dx        | 486         |      | Gp                 | 3     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 251    |
| 505         | 193             | 05/13/2014                     |                | Px        | 93010       |      | Gp                 | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                            | TEDN   | 251    |
| 506         | 193             | 05/13/2014                     |                | Px        | 99291       |      | Gp                 | 1     | Critical Care Ill/Injured Patient Init 30 |                        |             |     |                            | TEDN   | 252    |
| 507         | 193             | 05/13/2014                     |                | Dx        | 78791       | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                            | TEDN   | 253    |
| 508         | 193             | 05/13/2014                     |                | Dx        | 51881       | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                            | TEDN   | 253    |
| 509         | 193             | 05/13/2014                     |                | Dx        | 5168        | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                            | TEDN   | 253    |
| 510         | 193             | 05/13/2014                     |                | Dx        | 486         | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 253    |
| 511         | 193             | 05/13/2014                     |                | Px        | 99223       | Inpt | Fp                 | 1     | Initial Hospital Care/Day 70 Minutes      |                        |             |     |                            | TEDN   | 253    |
| 512         | 193             | 05/13/2014                     |                | Dx        | 486         | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                            | TEDN   | 254    |
| 513         | 193             | 05/13/2014                     |                | Px        | 71010       | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                            | TEDN   | 254    |
| 514         | 193             | 05/13/2014                     |                | Dx        | 78703       | Inpt | Grpract            | 1     | Vomiting Alone                            |                        |             |     |                            | TEDN   | 255    |
| 515         | 193             | 05/13/2014                     |                | Px        | 93010       | Inpt | Grpract            | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                            | TEDN   | 255    |
| 516         | 194             | 05/14/2014                     |                | Dx        | 41401       | Inpt | Cardvasc           | 1     | Atheroscler Native Coronary Art           |                        |             |     |                            | TEDN   | 256    |
| 517         | 194             | 05/14/2014                     |                | Dx        | 42731       | Inpt | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                            | TEDN   | 256    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 518         | 194             | 05/14/2014                     |                | Dx        | 4011  | Inpt | Cardvasc           | 3     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 256    |
| 519         | 194             | 05/14/2014                     |                | Dx        | 2722  | Inpt | Cardvasc           | 4     | Mixed Hyperlipidemia                      |                        |             |     |                  | TEDN   | 256    |
| 520         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 256    |
| 521         | 194             | 05/14/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 257    |
| 522         | 194             | 05/14/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 257    |
| 523         | 194             | 05/14/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 257    |
| 524         | 194             | 05/14/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 257    |
| 525         | 194             | 05/14/2014                     |                | Px        | 99233 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 35 Minutes         |                        |             |     |                  | TEDN   | 257    |
| 526         | 194             | 05/14/2014                     |                | Dx        | 486   | Inpt | Radio              | 1     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 258    |
| 527         | 194             | 05/14/2014                     |                | Px        | 71250 | Inpt | Radio              | 1     | Ct Thorax W/O Contrast Material           |                        |             |     |                  | TEDN   | 258    |
| 528         | 194             | 05/14/2014                     |                | Px        | 74176 | Inpt | Radio              | 1     | Ct Abdomen & Pelvis W/O Contrast Material |                        |             |     |                  | TEDN   | 259    |
| 529         | 194             | 05/14/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 260    |
| 530         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 260    |
| 531         | 194             | 05/14/2014                     |                | Px        | 99222 | Inpt | Grpprac            | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 261    |
| 532         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 0389  |      |                    | 1     | Uns Septicemia                            |                        |             |     |                  | TEDI   | 266    |
| 533         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 51881 |      |                    | 2     | Respiratory Failure                       |                        |             |     |                  | TEDI   | 266    |
| 534         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 486   |      |                    | 3     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDI   | 266    |
| 535         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 5168  |      |                    | 4     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDI   | 266    |
| 536         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 42731 |      |                    | 5     | Atrial Fibrillation                       |                        |             |     |                  | TEDI   | 266    |
| 537         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 412   |      |                    | 6     | Old Myocardial Infarction                 |                        |             |     |                  | TEDI   | 266    |
| 538         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 25000 |      |                    | 7     | Diabetes Uncompl Type II                  |                        |             |     |                  | TEDI   | 266    |
| 539         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 99591 |      |                    | 8     | Sepsis                                    |                        |             |     |                  | TEDI   | 266    |
| 540         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 53081 |      |                    | 9     | Esophageal Reflux                         |                        |             |     |                  | TEDI   | 266    |
| 541         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 4019  |      |                    | 10    | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 266    |
| 542         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 41401 |      |                    | 11    | Atheroscler Native Coronary Art           |                        |             |     |                  | TEDI   | 266    |
| 543         | 195             | 05/15/2014                     | 05/22/2014     | Dx        | 2724  |      |                    | 12    | Oth/Uns Hyperlipidemia                    |                        |             |     |                  | TEDI   | 266    |
| 544         | 195             | 05/15/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 262    |
| 545         | 195             | 05/15/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 262    |
| 546         | 195             | 05/15/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 262    |
| 547         | 195             | 05/15/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 262    |
| 548         | 195             | 05/15/2014                     |                | Px        | 99232 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 262    |
| 549         | 195             | 05/15/2014                     |                | Dx        | 79902 | Inpt | Radio              | 1     | Hypoxemia                                 |                        |             |     |                  | TEDN   | 263    |
| 550         | 195             | 05/15/2014                     |                | Dx        | 78079 | Inpt | Radio              | 2     | Other Malaise And Fatigue                 |                        |             |     |                  | TEDN   | 263    |
| 551         | 195             | 05/15/2014                     |                | Px        | 78582 | Inpt | Radio              | 1     | Pulmonary Ventilation & Perfusion Imaging |                        |             |     |                  | TEDN   | 263    |
| 552         | 195             | 05/15/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 264    |
| 553         | 195             | 05/15/2014                     |                | Px        | 99232 | Inpt | Grpprac            | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 264    |
| 554         | 195             | 05/15/2014                     |                | Px        | 71010 | Inpt | Grpprac            | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 265    |
| 555         | 196             | 05/16/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                                  |                        |             |     |                  | TEDN   | 267    |
| 556         | 196             | 05/16/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                       |                        |             |     |                  | TEDN   | 267    |
| 557         | 196             | 05/16/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy              |                        |             |     |                  | TEDN   | 267    |
| 558         | 196             | 05/16/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified            |                        |             |     |                  | TEDN   | 267    |
| 559         | 196             | 05/16/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 267    |
| 560         | 196             | 05/16/2014                     |                | Dx        | 28860 | Inpt | Grpprac            | 1     | Leukocytosis Unspecified                  |                        |             |     |                  | TEDN   | 268    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|--------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 561         | 196             | 05/16/2014                     |                | Px        | 99233 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 35 Minutes    |                        |             |     |                  | TEDN   | 268    |
| 562         | 196             | 05/16/2014                     |                | Px        | 71260 | Inpt | Grppract           | 1     | Ct Thorax W/Contrast Material        |                        |             |     |                  | TEDN   | 269    |
| 563         | 197             | 05/17/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 270    |
| 564         | 197             | 05/17/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 270    |
| 565         | 197             | 05/17/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 270    |
| 566         | 197             | 05/17/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 270    |
| 567         | 197             | 05/17/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 270    |
| 568         | 198             | 05/18/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 271    |
| 569         | 198             | 05/18/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 271    |
| 570         | 198             | 05/18/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 271    |
| 571         | 198             | 05/18/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 271    |
| 572         | 198             | 05/18/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 271    |
| 573         | 199             | 05/19/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 272    |
| 574         | 199             | 05/19/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 272    |
| 575         | 199             | 05/19/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 272    |
| 576         | 199             | 05/19/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 272    |
| 577         | 199             | 05/19/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 272    |
| 578         | 199             | 05/19/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 273    |
| 579         | 199             | 05/19/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 273    |
| 580         | 199             | 05/19/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 274    |
| 581         | 200             | 05/20/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 275    |
| 582         | 200             | 05/20/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 275    |
| 583         | 200             | 05/20/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 275    |
| 584         | 200             | 05/20/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 275    |
| 585         | 200             | 05/20/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 275    |
| 586         | 200             | 05/20/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 276    |
| 587         | 200             | 05/20/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 276    |
| 588         | 200             | 05/20/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 277    |
| 589         | 201             | 05/21/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 278    |
| 590         | 201             | 05/21/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 278    |
| 591         | 201             | 05/21/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 278    |
| 592         | 201             | 05/21/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 278    |
| 593         | 201             | 05/21/2014                     |                | Px        | 99231 | Inpt | Fp                 | 1     | Sbsq Hospital Care/Day 15 Minutes    |                        |             |     |                  | TEDN   | 278    |
| 594         | 201             | 05/21/2014                     |                | Dx        | 5183  | Inpt | Radio              | 1     | Pulmonary Eosinophilia               |                        |             |     |                  | TEDN   | 279    |
| 595         | 201             | 05/21/2014                     |                | Px        | 71250 | Inpt | Radio              | 1     | Ct Thorax W/O Contrast Material      |                        |             |     |                  | TEDN   | 279    |
| 596         | 201             | 05/21/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 280    |
| 597         | 201             | 05/21/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 280    |
| 598         | 201             | 05/21/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes    |                        |             |     |                  | TEDN   | 281    |
| 607         | 202             | 05/22/2014                     |                | Dx        | 78791 | Inpt | Fp                 | 1     | Diarrhea                             |                        |             |     |                  | TEDN   | 287    |
| 608         | 202             | 05/22/2014                     |                | Dx        | 51881 | Inpt | Fp                 | 2     | Respiratory Failure                  |                        |             |     |                  | TEDN   | 287    |
| 609         | 202             | 05/22/2014                     |                | Dx        | 5168  | Inpt | Fp                 | 3     | Other Alveolar Pneumonopathy         |                        |             |     |                  | TEDN   | 287    |
| 610         | 202             | 05/22/2014                     |                | Dx        | 486   | Inpt | Fp                 | 4     | Pneumonia Organism Unspecified       |                        |             |     |                  | TEDN   | 287    |
| 612         | 202             | 05/22/2014                     |                | Dx        | 28860 | Inpt | Grppract           | 1     | Leukocytosis Unspecified             |                        |             |     |                  | TEDN   | 290    |



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| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS  | Provider Specialty | Sesq # | Diagnosis/Procedure Code Description      | Medication Description  | Days Supply | QTY | Drug Formulation            | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|--------|-------------------------------------------|-------------------------|-------------|-----|-----------------------------|--------|--------|
| 613         | 202             | 05/22/2014                     |                | Px        | 99232       | Inpt | Grpract            | 1      | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                             | TEDN   | 290    |
| 614         | 202             | 05/22/2014                     |                | Px        | 99232       | Inpt | Grpract            | 1      | Sbsq Hospital Care/Day 25 Minutes         |                         |             |     |                             | TEDN   | 291    |
| 611         | 202             | 05/22/2014                     |                | Px        | 99238       | Inpt | Fp                 | 1      | Hospital Discharge Day Management 30 Min/ |                         |             |     |                             | TEDN   | 287    |
| 599         | 202             | 05/22/2014                     |                | Dx        | 79902       |      | Medic              | 1      | Hypoxemia                                 |                         |             |     |                             | TEDN   | 288    |
| 600         | 202             | 05/22/2014                     |                | Px        | E0431       |      | Medic              | 1      | Portable Gaseous O2                       |                         |             |     |                             | TEDN   | 288    |
| 601         | 202             | 05/22/2014                     |                | Px        | E1390       |      | Medic              | 1      | Oxygen Concentrator                       |                         |             |     |                             | TEDN   | 289    |
| 602         | 202             | 05/22/2014                     |                | Rx        | 59762306001 |      |                    |        |                                           | Azithromycin            | 8           | 12  | Tablet                      | PDTS   | 282    |
| 603         | 202             | 05/22/2014                     |                | Rx        | 00597002402 |      |                    |        |                                           | Combivent Respimat      | 25          | 4   | Aerosol W/Adapter (Gm)      | PDTS   | 283    |
| 604         | 202             | 05/22/2014                     |                | Rx        | 00603459315 |      |                    |        |                                           | Methylprednisolone      | 6           | 21  | Tablet, Dose Pack           | PDTS   | 284    |
| 605         | 202             | 05/22/2014                     |                | Rx        | 45802065087 |      |                    |        |                                           | Loratadine              | 30          | 30  | Tablet                      | PDTS   | 285    |
| 606         | 202             | 05/22/2014                     |                | Rx        | 64980015701 |      |                    |        |                                           | Vitamin D2              | 70          | 10  | Capsule (Hard, Soft, Etc.)  | PDTS   | 286    |
| 615         | 204             | 05/24/2014                     |                | Rx        | 68382002810 |      |                    |        |                                           | Metformin Hcl           | 90          | 90  | Tablet                      | PDTS   | 292    |
| 616         | 207             | 05/27/2014                     |                | Rx        | 00603646832 |      |                    |        |                                           | Zolpidem Tartrate       | 30          | 30  | Tablet                      | PDTS   | 293    |
| 617         | 212             | 06/01/2014                     |                | Dx        | 7213        |      | Radio              | 1      | Lumbosacral Spondylosis                   |                         |             |     |                             | TEDN   | 294    |
| 618         | 212             | 06/01/2014                     |                | Dx        | 7242        |      | Radio              | 2      | Lumbago                                   |                         |             |     |                             | TEDN   | 294    |
| 619         | 212             | 06/01/2014                     |                | Px        | 72131       |      | Radio              | 1      | Ct Lumbar Spine W/O Contrast Material     |                         |             |     |                             | TEDN   | 294    |
| 620         | 212             | 06/01/2014                     |                | Px        | 71010       |      | Radio              | 1      | Radiologic Examination Chest Single View  |                         |             |     |                             | TEDN   | 295    |
| 621         | 212             | 06/01/2014                     |                | Dx        | 7242        |      | Grpract            | 1      | Lumbago                                   |                         |             |     |                             | TEDN   | 296    |
| 622         | 212             | 06/01/2014                     |                | Px        | 99285       |      | Grpract            | 1      | Emergency Dept Visit High Severity&threat |                         |             |     |                             | TEDN   | 296    |
| 623         | 212             | 06/01/2014                     |                | Dx        | 33819       |      | Facility           | 1      | Other Acute Pain                          |                         |             |     |                             | TEDN   | 297    |
| 624         | 212             | 06/01/2014                     |                | Dx        | 7245        |      | Facility           | 2      | Backache Unspecified                      |                         |             |     |                             | TEDN   | 297    |
| 625         | 212             | 06/01/2014                     |                | Dx        | 4019        |      | Facility           | 3      | Unspecified Essential Hypertension        |                         |             |     |                             | TEDN   | 297    |
| 626         | 212             | 06/01/2014                     |                | Dx        | 25000       |      | Facility           | 4      | Diabetes Uncompl Type Ii                  |                         |             |     |                             | TEDN   | 297    |
| 627         | 212             | 06/01/2014                     |                | Dx        | 53081       |      | Facility           | 5      | Esophageal Reflux                         |                         |             |     |                             | TEDN   | 297    |
| 628         | 212             | 06/01/2014                     |                | Dx        | 42731       |      | Facility           | 6      | Atrial Fibrillation                       |                         |             |     |                             | TEDN   | 297    |
| 629         | 212             | 06/01/2014                     |                | Px        | 71010       |      | Facility           | 1      | Radiologic Examination Chest Single View  |                         |             |     |                             | TEDN   | 297    |
| 630         | 212             | 06/01/2014                     |                | Px        | 72131       |      | Facility           | 1      | Ct Lumbar Spine W/O Contrast Material     |                         |             |     |                             | TEDN   | 298    |
| 631         | 212             | 06/01/2014                     |                | Px        | 81001       |      | Facility           | 1      | Urnl Dip Stick/Tablet Reagent Auto Micro  |                         |             |     |                             | TEDN   | 299    |
| 632         | 212             | 06/01/2014                     |                | Px        | 87086       |      | Facility           | 1      | Culture Bacterial Quanttative Colony Coun |                         |             |     |                             | TEDN   | 300    |
| 633         | 212             | 06/01/2014                     |                | Px        | 93005       |      | Facility           | 1      | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                         |             |     |                             | TEDN   | 301    |
| 634         | 212             | 06/01/2014                     |                | Px        | 99281       |      | Facility           | 1      | Emergency Department Visit Limited/Minor  |                         |             |     |                             | TEDN   | 302    |
| 635         | 212             | 06/01/2014                     |                | Px        | 99283       |      | Facility           | 1      | Emergency Department Visit Moderate Sever |                         |             |     |                             | TEDN   | 303    |
| 636         | 212             | 06/01/2014                     |                | Px        | C9399       |      | Facility           | 1      | Unclassified Drugs Or Biolog              |                         |             |     |                             | TEDN   | 304    |
| 637         | 213             | 06/02/2014                     |                | Rx        | 00406051205 |      |                    |        |                                           | Oxycodone-Acetaminophen | 3           | 12  | Tablet                      | PDTS   | 305    |
| 638         | 217             | 06/06/2014                     |                | Rx        | 00071101468 |      |                    |        |                                           | Lyrica                  | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 306    |
| 639         | 222             | 06/11/2014                     |                | Dx        | 72252       |      | Ortho              | 1      | Degener Lumbar/Lumbosacral Iv Disc        |                         |             |     |                             | TEDN   | 313    |
| 640         | 222             | 06/11/2014                     |                | Dx        | 7213        |      | Ortho              | 2      | Lumbosacral Spondylosis                   |                         |             |     |                             | TEDN   | 313    |
| 641         | 222             | 06/11/2014                     |                | Px        | 99214       |      | Ortho              | 1      | Office Outpatient Visit 25 Minutes        |                         |             |     |                             | TEDN   | 313    |
| 642         | 222             | 06/11/2014                     |                | Rx        | 00310075290 |      |                    |        |                                           | Crestor                 | 90          | 90  | Tablet                      | PDTS   | 307    |
| 643         | 222             | 06/11/2014                     |                | Rx        | 00008084181 |      |                    |        |                                           | Protonix                | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 308    |
| 644         | 222             | 06/11/2014                     |                | Rx        | 00009519103 |      |                    |        |                                           | Detrol La               | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 309    |
| 645         | 222             | 06/11/2014                     |                | Rx        | 65162062711 |      |                    |        |                                           | Tramadol Hcl            | 30          | 90  | Tablet                      | PDTS   | 310    |
| 646         | 222             | 06/11/2014                     |                | Rx        | 00603258221 |      |                    |        |                                           | Carisoprodol            | 30          | 90  | Tablet                      | PDTS   | 311    |

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|-------------|-----------------|--------------------------------|----------------|-----------|---------------|-----|--------------------|-------|------------------------------------------|----------------------------|-------------|-----|--------------------------------|--------|--------|
| 647         | 222             | 06/11/2014                     |                | Rx        | 00378108901   |     |                    |       |                                          | Meloxicam                  | 90          | 90  | Tablet                         | PDTS   | 312    |
| 648         | 229             | 06/18/2014                     |                | Dx        | 7823          |     | Fp                 | 1     | Edema                                    |                            |             |     |                                | TEDN   | 314    |
| 649         | 229             | 06/18/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes       |                            |             |     |                                | TEDN   | 314    |
| 650         | 230             | 06/19/2014                     |                | Rx        | 00781196610   |     |                    |       |                                          | Furosemide                 | 30          | 15  | Tablet                         | PDTS   | 315    |
| 651         | 230             | 06/19/2014                     |                | Rx        | 00781572010   |     |                    |       |                                          | Potassium Chloride         | 30          | 15  | Tablet, SR, particles/Crystals | PDTS   | 316    |
| 652         | 233             | 06/22/2014                     |                | Dx        | 79902         |     | Medic              | 1     | Hypoxemia                                |                            |             |     |                                | TEDN   | 317    |
| 653         | 233             | 06/22/2014                     |                | Px        | E0431         |     | Medic              | 1     | Portable Gaseous O2                      |                            |             |     |                                | TEDN   | 317    |
| 654         | 233             | 06/22/2014                     |                | Px        | E1390         |     | Medic              | 1     | Oxygen Concentrator                      |                            |             |     |                                | TEDN   | 318    |
| 655         | 238             | 06/27/2014                     |                | Dx        | 42731         |     | Cardvasc           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 321    |
| 656         | 238             | 06/27/2014                     |                | Dx        | 4011          |     | Cardvasc           | 2     | Benign Essential Hypertension            |                            |             |     |                                | TEDN   | 321    |
| 657         | 238             | 06/27/2014                     |                | Dx        | 41401         |     | Cardvasc           | 3     | Atheroscler Native Coronary Art          |                            |             |     |                                | TEDN   | 321    |
| 658         | 238             | 06/27/2014                     |                | Dx        | 496           |     | Cardvasc           | 4     | Chronic Airway Obstruction Other         |                            |             |     |                                | TEDN   | 321    |
| 659         | 238             | 06/27/2014                     |                | Px        | 99215         |     | Cardvasc           | 1     | Office Outpatient Visit 40 Minutes       |                            |             |     |                                | TEDN   | 321    |
| 660         | 238             | 06/27/2014                     |                | Rx        | 64679073402   |     |                    |       |                                          | Metoprolol Succinate       | 90          | 90  | Tablet, SR 24hr                | PDTS   | 319    |
| 661         | 238             | 06/27/2014                     |                | Rx        | NI Study Drug |     |                    |       |                                          | Non-Index Study Drug       | 90          |     | INITIAL FILL                   | PDTS   | 320    |
| 662         | 243             | 07/02/2014                     |                | Dx        | 42731         |     | Grppract           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 322    |
| 663         | 243             | 07/02/2014                     |                | Px        | 93010         |     | Grppract           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only  |                            |             |     |                                | TEDN   | 322    |
| 664         | 243             | 07/02/2014                     |                | Dx        | 42731         |     | Facility           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 323    |
| 665         | 243             | 07/02/2014                     |                | Px        | 93005         |     | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only |                            |             |     |                                | TEDN   | 323    |
| 666         | 248             | 07/07/2014                     |                | Rx        | 00071101468   |     |                    |       |                                          | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)     | PDTS   | 324    |
| 667         | 266             | 07/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                          | Eliquis                    | 30          | 60  | Tablet                         | PDTS   | 325    |
| 668         | 269             | 07/28/2014                     |                | Dx        | 25060         |     | Podia              | 1     | Diabetes Neuro Manif Type Ii             |                            |             |     |                                | TEDN   | 328    |
| 669         | 269             | 07/28/2014                     |                | Dx        | 7030          |     | Podia              | 2     | Ingrowing Nail                           |                            |             |     |                                | TEDN   | 328    |
| 670         | 269             | 07/28/2014                     |                | Dx        | 1101          |     | Podia              | 3     | Dermatophytosis Nail                     |                            |             |     |                                | TEDN   | 328    |
| 671         | 269             | 07/28/2014                     |                | Dx        | 7039          |     | Podia              | 4     | Unspec Disease Nail                      |                            |             |     |                                | TEDN   | 328    |
| 672         | 269             | 07/28/2014                     |                | Dx        | 3556          |     | Podia              | 5     | Lesion Plantar Nerve                     |                            |             |     |                                | TEDN   | 328    |
| 673         | 269             | 07/28/2014                     |                | Dx        | 73037         |     | Podia              | 6     | Periostitis Ankle/Foot                   |                            |             |     |                                | TEDN   | 328    |
| 674         | 269             | 07/28/2014                     |                | Dx        | 73399         |     | Podia              | 7     | Other Disorders Bone/Cartilage           |                            |             |     |                                | TEDN   | 328    |
| 675         | 269             | 07/28/2014                     |                | Px        | 11719         |     | Podia              | 1     | Trimming Nondystrophic Nails Any Number  |                            |             |     |                                | TEDN   | 328    |
| 676         | 269             | 07/28/2014                     |                | Px        | 11720         |     | Podia              | 1     | Debridement Nail Any Method 1-5          |                            |             |     |                                | TEDN   | 329    |
| 677         | 269             | 07/28/2014                     |                | Px        | 99212         |     | Podia              | 1     | Office Outpatient Visit 10 Minutes       |                            |             |     |                                | TEDN   | 330    |
| 678         | 269             | 07/28/2014                     |                | Rx        | 00003089421   |     |                    |       |                                          | Eliquis                    | 30          | 60  | Tablet                         | PDTS   | 326    |
| 679         | 269             | 07/28/2014                     |                | Rx        | 00078037905   |     |                    |       |                                          | Lotrel                     | 90          | 90  | Capsule (Hard, Soft, Etc.)     | PDTS   | 327    |
| 680         | 277             | 08/05/2014                     |                | Rx        | 00904584940   |     |                    |       |                                          | Metformin Hcl              | 90          | 90  | Tablet                         | PDTS   | 331    |
| 681         | 283             | 08/11/2014                     |                | Rx        | 00071101468   |     |                    |       |                                          | Lyrica                     | 30          | 60  | Capsule (Hard, Soft, Etc.)     | PDTS   | 332    |
| 682         | 284             | 08/12/2014                     |                | Rx        | 66993089845   |     |                    |       |                                          | Clotrimazole-Betamethasone | 7           | 45  | Cream (Grams)                  | PDTS   | 333    |
| 683         | 286             | 08/14/2014                     |                | Dx        | 42731         |     | Cardvasc           | 1     | Atrial Fibrillation                      |                            |             |     |                                | TEDN   | 334    |
| 684         | 286             | 08/14/2014                     |                | Dx        | 4011          |     | Cardvasc           | 2     | Benign Essential Hypertension            |                            |             |     |                                | TEDN   | 334    |
| 685         | 286             | 08/14/2014                     |                | Dx        | 41401         |     | Cardvasc           | 3     | Atheroscler Native Coronary Art          |                            |             |     |                                | TEDN   | 334    |
| 686         | 286             | 08/14/2014                     |                | Dx        | 496           |     | Cardvasc           | 4     | Chronic Airway Obstruction Other         |                            |             |     |                                | TEDN   | 334    |
| 687         | 286             | 08/14/2014                     |                | Px        | 99214         |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes       |                            |             |     |                                | TEDN   | 334    |
| 688         | 301             | 08/29/2014                     |                | Dx        | 25000         |     | Fp                 | 1     | Diabetes Uncompl Type Ii                 |                            |             |     |                                | TEDN   | 338    |
| 689         | 301             | 08/29/2014                     |                | Dx        | 2810          |     | Fp                 | 2     | Pernicious Anemia                        |                            |             |     |                                | TEDN   | 338    |

Patient ID: ILD-0075

Age: 72 Gender: F Indexdate: 11/01/2013 Event Date: 05/15/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code          | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description       | Medication Description      | Days Supply | QTY | Drug Formulation            | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|---------------|-----|--------------------|-------|--------------------------------------------|-----------------------------|-------------|-----|-----------------------------|--------|--------|
| 690         | 301             | 08/29/2014                     |                | Dx        | 4659          |     | Fp                 | 3     | Acute Upper Resp Infections Uns            |                             |             |     |                             | TEDN   | 338    |
| 691         | 301             | 08/29/2014                     |                | Dx        | 460           |     | Fp                 | 4     | Acute Nasopharyngitis                      |                             |             |     |                             | TEDN   | 338    |
| 692         | 301             | 08/29/2014                     |                | Px        | 80053         |     | Fp                 | 1     | Comprehensive Metabolic Panel              |                             |             |     |                             | TEDN   | 338    |
| 693         | 301             | 08/29/2014                     |                | Px        | 85025         |     | Fp                 | 1     | Blood Count Complete Auto&auto Difrntrl Wb |                             |             |     |                             | TEDN   | 339    |
| 694         | 301             | 08/29/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                             | TEDN   | 340    |
| 695         | 301             | 08/29/2014                     |                | Rx        | 59746012110   |     |                    |       |                                            | Meclizine Hcl               | 10          | 40  | Tablet                      | PDTS   | 335    |
| 696         | 301             | 08/29/2014                     |                | Rx        | 00378363705   |     |                    |       |                                            | Cetirizine Hcl              | 30          | 30  | Tablet                      | PDTS   | 336    |
| 697         | 301             | 08/29/2014                     |                | Rx        | 00781261305   |     |                    |       |                                            | Amoxicillin                 | 10          | 30  | Capsule (Hard, Soft, Etc.)  | PDTS   | 337    |
| 698         | 306             | 09/03/2014                     |                | Rx        | 0             |     |                    |       |                                            | Compounded Medication       | 10          | 240 |                             | PDTS   | 341    |
| 699         | 311             | 09/08/2014                     |                | Dx        | 4659          |     | Fp                 | 1     | Acute Upper Resp Infections Uns            |                             |             |     |                             | TEDN   | 345    |
| 700         | 311             | 09/08/2014                     |                | Dx        | 25000         |     | Fp                 | 2     | Diabetes Uncompl Type Ii                   |                             |             |     |                             | TEDN   | 345    |
| 701         | 311             | 09/08/2014                     |                | Px        | 99213         |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes         |                             |             |     |                             | TEDN   | 345    |
| 702         | 311             | 09/08/2014                     |                | Rx        | 00093227534   |     |                    |       |                                            | Amox Tr-Potassium Clavulana | 10          | 20  | Tablet                      | PDTS   | 342    |
| 703         | 311             | 09/08/2014                     |                | Rx        | 14550051204   |     |                    |       |                                            | Gabapentin                  | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 343    |
| 704         | 311             | 09/08/2014                     |                | Rx        | 57664018534   |     |                    |       |                                            | Promethazine-Codeine        | 18          | 180 | Syrup                       | PDTS   | 344    |
| 705         | 326             | 09/23/2014                     |                | Rx        | 68001016208   |     |                    |       |                                            | Promethazine Hcl            | 10          | 30  | Tablet                      | PDTS   | 346    |
| 706         | 327             | 09/24/2014                     |                | Rx        | NI Study Drug |     |                    |       |                                            | Non-Index Study Drug        | 90          |     | REFILL                      | PDTS   | 347    |
| 707         | 328             | 09/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                            | Eliquis                     | 30          | 60  | Tablet                      | PDTS   | 348    |
| 708         | 328             | 09/25/2014                     |                | Rx        | 00009519103   |     |                    |       |                                            | Detrol La                   | 90          | 90  | Capsule, SR 24 Hr           | PDTS   | 349    |
| 709         | 328             | 09/25/2014                     |                | Rx        | 00008084181   |     |                    |       |                                            | Protonix                    | 90          | 180 | Tablet, DR (Enteric Coated) | PDTS   | 350    |
| 710         | 328             | 09/25/2014                     |                | Rx        | 00003089421   |     |                    |       |                                            | Eliquis                     | 30          | 60  | Tablet                      | PDTS   | 351    |
| 711         | 328             | 09/25/2014                     |                | Rx        | 00310075290   |     |                    |       |                                            | Crestor                     | 90          | 90  | Tablet                      | PDTS   | 352    |
| 712         | 329             | 09/26/2014                     |                | Rx        | 00071101468   |     |                    |       |                                            | Lyrica                      | 30          | 60  | Capsule (Hard, Soft, Etc.)  | PDTS   | 353    |

End of Profile



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Age: 71 Gender: F Indexdate: 10/03/2011 Event Date: 07/16/2014 Date of Death:

| Line Number | Time from Index | Date of Service/<br>Admit Date | Discharge Date | Code Type | Code        | POS | Provider Specialty | Seq # | Diagnosis/Procedure Code Description     | Medication Description      | Days Supply | QTY | Drug Formulation              | Source | Record |
|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|------------------------------------------|-----------------------------|-------------|-----|-------------------------------|--------|--------|
| 1           | -329            | 11/08/2010                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 1      |
| 2           | -307            | 11/30/2010                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 2      |
| 3           | -307            | 11/30/2010                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 3      |
| 4           | -307            | 11/30/2010                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 4      |
| 5           | -294            | 12/13/2010                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 5      |
| 6           | -278            | 12/29/2010                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 6      |
| 7           | -266            | 01/10/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 30          | 30  | Tablet                        | PDTS   | 7      |
| 8           | -235            | 02/10/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 90          | 90  | Tablet                        | PDTS   | 8      |
| 9           | -229            | 02/16/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 9      |
| 10          | -229            | 02/16/2011                     |                | Px        | A7032       |     | Medic              | 1     | Replacement Nasal Cushion                |                             |             |     |                               | TEDN   | 9      |
| 11          | -229            | 02/16/2011                     |                | Px        | A7034       |     | Medic              | 1     | Nasal Application Device                 |                             |             |     |                               | TEDN   | 10     |
| 12          | -229            | 02/16/2011                     |                | Px        | A7035       |     | Medic              | 1     | Pos Airway Press Headgear                |                             |             |     |                               | TEDN   | 11     |
| 13          | -229            | 02/16/2011                     |                | Px        | A7037       |     | Medic              | 1     | Pos Airway Pressure Tubing               |                             |             |     |                               | TEDN   | 12     |
| 14          | -217            | 02/28/2011                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 13     |
| 15          | -217            | 02/28/2011                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 14     |
| 16          | -217            | 02/28/2011                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 15     |
| 17          | -185            | 04/01/2011                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 16     |
| 18          | -166            | 04/20/2011                     |                | Dx        | 496         |     | Medic              | 1     | Chronic Airway Obstruction Other         |                             |             |     |                               | TEDN   | 17     |
| 19          | -166            | 04/20/2011                     |                | Px        | J7620       |     | Medic              | 1     | Albuterol Ipratrop Non-Comp              |                             |             |     |                               | TEDN   | 17     |
| 20          | -166            | 04/20/2011                     |                | Px        | Q0513       |     | Medic              | 1     | Disp Fee Inhal Drugs/30 Days             |                             |             |     |                               | TEDN   | 18     |
| 21          | -165            | 04/21/2011                     |                | Dx        | 32723       |     | Indeplab           | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 19     |
| 22          | -165            | 04/21/2011                     |                | Px        | 94762       |     | Indeplab           | 1     | Noninvasive Ear/Pulse Oximetry Overnight |                             |             |     |                               | TEDN   | 19     |
| 23          | -159            | 04/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 20     |
| 24          | -159            | 04/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 20     |
| 25          | -140            | 05/16/2011                     |                | Rx        | 00527134210 |     |                    |       |                                          | Levothyroxine Sodium        | 90          | 90  | Tablet                        | PDTS   | 21     |
| 26          | -130            | 05/26/2011                     |                | Rx        | 68462055401 |     |                    |       |                                          | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                        | PDTS   | 22     |
| 27          | -129            | 05/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 24     |
| 28          | -129            | 05/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 24     |
| 29          | -129            | 05/27/2011                     |                | Rx        | 00186504031 |     |                    |       |                                          | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)  | PDTS   | 23     |
| 30          | -124            | 06/01/2011                     |                | Rx        | 00093718856 |     |                    |       |                                          | Fluoxetine Hcl              | 90          | 90  | Tablet                        | PDTS   | 25     |
| 31          | -101            | 06/24/2011                     |                | Rx        | 59310057920 |     |                    |       |                                          | Proair Hfa                  | 25          | 9   | Hfa Aerosol With Adapter (Gm) | PDTS   | 26     |
| 32          | -101            | 06/24/2011                     |                | Rx        | 00085128801 |     |                    |       |                                          | Nasonex                     | 30          | 17  | Aerosol, Spray W/Pump (Gm)    | PDTS   | 27     |
| 33          | -98             | 06/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 28     |
| 34          | -98             | 06/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 28     |
| 35          | -96             | 06/29/2011                     |                | Rx        | 68180075203 |     |                    |       |                                          | Amlodipine Besylate         | 90          | 90  | Tablet                        | PDTS   | 29     |
| 36          | -68             | 07/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                  |                             |             |     |                               | TEDN   | 30     |
| 37          | -68             | 07/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                      |                             |             |     |                               | TEDN   | 30     |
| 38          | -49             | 08/15/2011                     |                | Dx        | 2449        |     | Fp                 | 1     | Uns Hypothyroidism                       |                             |             |     |                               | TEDN   | 37     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 39          | -49             | 08/15/2011                     |                | Dx        | 69010       |     | Fp                 | 2     | Uns Seborrheic Dermatitis                 |                             |             |     |                              | TEDN   | 37     |
| 40          | -49             | 08/15/2011                     |                | Dx        | 79021       |     | Fp                 | 3     | Impaired Fasting Glucose                  |                             |             |     |                              | TEDN   | 37     |
| 41          | -49             | 08/15/2011                     |                | Dx        | 4019        |     | Fp                 | 4     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 37     |
| 42          | -49             | 08/15/2011                     |                | Px        | 99213       |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 37     |
| 43          | -49             | 08/15/2011                     |                | Rx        | 00085128801 |     |                    |       |                                           | Nasonex                     | 30          | 17  | Aerosol, Spray W/Pump (Gm)   | PDTS   | 31     |
| 44          | -49             | 08/15/2011                     |                | Rx        | 00186504031 |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 32     |
| 45          | -49             | 08/15/2011                     |                | Rx        | 65862019201 |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 33     |
| 46          | -49             | 08/15/2011                     |                | Rx        | 00527134210 |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 34     |
| 47          | -49             | 08/15/2011                     |                | Rx        | 45802046564 |     |                    |       |                                           | Ketoconazole                | 30          | 240 | Shampoo                      | PDTS   | 35     |
| 48          | -49             | 08/15/2011                     |                | Rx        | 68462055401 |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 36     |
| 49          | -39             | 08/25/2011                     |                | Dx        | 4011        |     | Cardvasc           | 1     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 41     |
| 50          | -39             | 08/25/2011                     |                | Dx        | 42731       |     | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 41     |
| 51          | -39             | 08/25/2011                     |                | Dx        | 2865        |     | Cardvasc           | 3     | Intrin Circ Anticoag Hemorr Dis           |                             |             |     |                              | TEDN   | 41     |
| 52          | -39             | 08/25/2011                     |                | Px        | 93000       |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                             |             |     |                              | TEDN   | 41     |
| 53          | -39             | 08/25/2011                     |                | Px        | 99214       |     | Cardvasc           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 42     |
| 54          | -39             | 08/25/2011                     |                | Rx        | 62037059990 |     |                    |       |                                           | Cartia Xt                   | 90          | 90  | Capsule, SR 24 Hr            | PDTS   | 38     |
| 55          | -39             | 08/25/2011                     |                | Rx        | 00527132410 |     |                    |       |                                           | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 39     |
| 56          | -39             | 08/25/2011                     |                | Rx        | 51672403201 |     |                    |       |                                           | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 40     |
| 57          | -37             | 08/27/2011                     |                | Dx        | 32723       |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 43     |
| 58          | -37             | 08/27/2011                     |                | Px        | E1390       |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 43     |
| 59          | -35             | 08/29/2011                     |                | Dx        | V5861       |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 44     |
| 60          | -35             | 08/29/2011                     |                | Dx        | 42731       |     | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 44     |
| 61          | -35             | 08/29/2011                     |                | Px        | 85610       |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 44     |
| 62          | -35             | 08/29/2011                     |                | Px        | 99211       |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 45     |
| 72          | -29             | 09/04/2011                     |                | Dx        | 42731       |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 47     |
| 73          | -29             | 09/04/2011                     |                | Px        | 93010       |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                             |             |     |                              | TEDN   | 47     |
| 63          | -29             | 09/04/2011                     |                | Dx        | 5789        |     | Gp                 | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                              | TEDN   | 46     |
| 64          | -29             | 09/04/2011                     |                | Dx        | 5693        |     | Gp                 | 2     | Hemorrhage Rectum/Anus                    |                             |             |     |                              | TEDN   | 46     |
| 65          | -29             | 09/04/2011                     |                | Dx        | 42731       |     | Gp                 | 3     | Atrial Fibrillation                       |                             |             |     |                              | TEDN   | 46     |
| 66          | -29             | 09/04/2011                     |                | Dx        | 53081       |     | Gp                 | 4     | Esophageal Reflux                         |                             |             |     |                              | TEDN   | 46     |
| 67          | -29             | 09/04/2011                     |                | Dx        | 2449        |     | Gp                 | 5     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 46     |
| 68          | -29             | 09/04/2011                     |                | Dx        | 4019        |     | Gp                 | 6     | Unspecified Essential Hypertension        |                             |             |     |                              | TEDN   | 46     |
| 69          | -29             | 09/04/2011                     |                | Dx        | 56210       |     | Gp                 | 7     | Diverticulosis Colon                      |                             |             |     |                              | TEDN   | 46     |
| 70          | -29             | 09/04/2011                     |                | Dx        | V4586       |     | Gp                 | 8     | Bariatric Surgery Status                  |                             |             |     |                              | TEDN   | 46     |
| 71          | -29             | 09/04/2011                     |                | Px        | 99283       |     | Gp                 | 1     | Emergency Department Visit Moderate Sever |                             |             |     |                              | TEDN   | 46     |
| 74          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 5789        |     |                    | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                              | TEDI   | 50     |
| 75          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 42731       |     |                    | 2     | Atrial Fibrillation                       |                             |             |     |                              | TEDI   | 50     |
| 76          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 53081       |     |                    | 3     | Esophageal Reflux                         |                             |             |     |                              | TEDI   | 50     |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 77          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 2449  |      |                    | 4     | Uns Hypothyroidism                        |                        |             |     |                  | TEDI   | 50     |
| 78          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 4019  |      |                    | 5     | Unspecified Essential Hypertension        |                        |             |     |                  | TEDI   | 50     |
| 79          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | 56210 |      |                    | 6     | Diverticulosis Colon                      |                        |             |     |                  | TEDI   | 50     |
| 80          | -29             | 09/04/2011                     | 09/07/2011     | Dx        | V4586 |      |                    | 7     | Bariatric Surgery Status                  |                        |             |     |                  | TEDI   | 50     |
| 81          | -29             | 09/04/2011                     | 09/07/2011     | Px        | 4513  |      |                    | 1     | Sm Bowel Endoscopy Other Spec             |                        |             |     |                  | TEDI   | 50     |
| 82          | -29             | 09/04/2011                     | 09/07/2011     | Px        | 4523  |      |                    | 2     | Colonoscopy                               |                        |             |     |                  | TEDI   | 50     |
| 83          | -29             | 09/04/2011                     |                | Px        | 99222 | Inpt | Cardvasc           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 48     |
| 84          | -29             | 09/04/2011                     |                | Dx        | 78650 | Inpt | Radio              | 1     | Unspec Chest Pain                         |                        |             |     |                  | TEDN   | 49     |
| 85          | -29             | 09/04/2011                     |                | Px        | 71010 | Inpt | Radio              | 1     | Radiologic Examination Chest Single View  |                        |             |     |                  | TEDN   | 49     |
| 86          | -27             | 09/06/2011                     |                | Dx        | 5789  | Inpt | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 51     |
| 87          | -27             | 09/06/2011                     |                | Dx        | 56210 | Inpt | Grppract           | 2     | Diverticulosis Colon                      |                        |             |     |                  | TEDN   | 51     |
| 88          | -27             | 09/06/2011                     |                | Px        | 43235 | Inpt | Grppract           | 1     | Upper Gi Ndsc Dx W/Wo Collection Specimen |                        |             |     |                  | TEDN   | 51     |
| 89          | -27             | 09/06/2011                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 52     |
| 90          | -26             | 09/07/2011                     |                | Dx        | 5789  | Inpt | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 53     |
| 91          | -26             | 09/07/2011                     |                | Dx        | 56210 | Inpt | Grppract           | 2     | Diverticulosis Colon                      |                        |             |     |                  | TEDN   | 53     |
| 92          | -26             | 09/07/2011                     |                | Px        | 45378 | Inpt | Grppract           | 1     | Colonoscopy Flx Dx W/Wo Collj Specimens   |                        |             |     |                  | TEDN   | 53     |
| 93          | -18             | 09/15/2011                     |                | Dx        | 4011  |      | Cardvasc           | 1     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 54     |
| 94          | -18             | 09/15/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 54     |
| 95          | -18             | 09/15/2011                     |                | Px        | 93000 |      | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                        |             |     |                  | TEDN   | 54     |
| 96          | -18             | 09/15/2011                     |                | Px        | 99213 |      | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                  | TEDN   | 55     |
| 97          | -14             | 09/19/2011                     |                | Dx        | 42731 |      | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 56     |
| 98          | -14             | 09/19/2011                     |                | Dx        | 4011  |      | Cardvasc           | 2     | Benign Essential Hypertension             |                        |             |     |                  | TEDN   | 56     |
| 99          | -14             | 09/19/2011                     |                | Px        | 93312 |      | Cardvasc           | 1     | Ecg Transesophag R-T 2d W/Prb Img Acquisj |                        |             |     |                  | TEDN   | 56     |
| 100         | -14             | 09/19/2011                     |                | Px        | 93320 |      | Cardvasc           | 1     | Doppler Echocard Pulse Wave W/Spectral Di |                        |             |     |                  | TEDN   | 57     |
| 101         | -14             | 09/19/2011                     |                | Px        | 93325 |      | Cardvasc           | 1     | Dop Echocard Color Flow Velocity Mapping  |                        |             |     |                  | TEDN   | 58     |
| 102         | -14             | 09/19/2011                     |                | Dx        | 42731 |      | Facility           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 59     |
| 103         | -14             | 09/19/2011                     |                | Dx        | V641  |      | Facility           | 2     | Px Not Done Contraindication              |                        |             |     |                  | TEDN   | 59     |
| 104         | -14             | 09/19/2011                     |                | Px        | 93005 |      | Facility           | 1     | Ecg Routine Ecg W/Least 12 Lds Trcg Only  |                        |             |     |                  | TEDN   | 59     |
| 105         | -12             | 09/21/2011                     |                | Dx        | V5861 |      | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 60     |
| 106         | -12             | 09/21/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 60     |
| 107         | -12             | 09/21/2011                     |                | Px        | 85610 |      | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 60     |
| 108         | -12             | 09/21/2011                     |                | Px        | 99211 |      | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 61     |
| 109         | -6              | 09/27/2011                     |                | Dx        | 32723 |      | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                  | TEDN   | 62     |
| 110         | -6              | 09/27/2011                     |                | Px        | E1390 |      | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                  | TEDN   | 62     |
| 111         | -5              | 09/28/2011                     |                | Dx        | V5861 |      | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                  | TEDN   | 63     |
| 112         | -5              | 09/28/2011                     |                | Dx        | 42731 |      | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 63     |
| 113         | -5              | 09/28/2011                     |                | Px        | 85610 |      | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                  | TEDN   | 63     |
| 114         | -5              | 09/28/2011                     |                | Px        | 99211 |      | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                  | TEDN   | 64     |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 115         | 0               | 10/03/2011                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 66     |
| 116         | 0               | 10/03/2011                     |                | Dx        | 28652            |     | Cardvasc           | 2     | Acquired Hemophilia                  |                             |             |     |                              | TEDN   | 66     |
| 117         | 0               | 10/03/2011                     |                | Px        | 93000            |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r |                             |             |     |                              | TEDN   | 66     |
| 118         | 0               | 10/03/2011                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes   |                             |             |     |                              | TEDN   | 67     |
| 119         | 0               | 10/03/2011                     | INDEX DATE     | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | INITIAL FILL                 | PDTS   | 65     |
| 120         | 8               | 10/11/2011                     |                | Rx        | 51672403201      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 68     |
| 121         | 16              | 10/19/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 69     |
| 122         | 16              | 10/19/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 69     |
| 123         | 16              | 10/19/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 69     |
| 124         | 16              | 10/19/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 70     |
| 125         | 23              | 10/26/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 71     |
| 126         | 23              | 10/26/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 71     |
| 127         | 23              | 10/26/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 71     |
| 128         | 23              | 10/26/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 72     |
| 129         | 24              | 10/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 73     |
| 130         | 24              | 10/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 73     |
| 131         | 35              | 11/07/2011                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 74     |
| 132         | 35              | 11/07/2011                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis   |                             |             |     |                              | TEDN   | 74     |
| 133         | 35              | 11/07/2011                     |                | Px        | 99212            |     | Cardvasc           | 1     | Office Outpatient Visit 10 Minutes   |                             |             |     |                              | TEDN   | 74     |
| 134         | 50              | 11/22/2011                     |                | Rx        | 00527132410      |     |                    |       |                                      | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 75     |
| 135         | 50              | 11/22/2011                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 76     |
| 136         | 55              | 11/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 77     |
| 137         | 55              | 11/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 77     |
| 138         | 56              | 11/28/2011                     |                | Rx        | 65862019201      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 78     |
| 139         | 57              | 11/29/2011                     |                | Rx        | 59762525004      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 79     |
| 140         | 57              | 11/29/2011                     |                | Rx        | 00186504031      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 80     |
| 141         | 59              | 12/01/2011                     |                | Rx        | 51672403201      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 81     |
| 142         | 63              | 12/05/2011                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 82     |
| 143         | 63              | 12/05/2011                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 82     |
| 144         | 63              | 12/05/2011                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 82     |
| 145         | 63              | 12/05/2011                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 83     |
| 146         | 78              | 12/20/2011                     |                | Rx        | 00527134210      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 84     |
| 147         | 84              | 12/26/2011                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 85     |
| 148         | 85              | 12/27/2011                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 86     |
| 149         | 85              | 12/27/2011                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 86     |
| 150         | 98              | 01/09/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 87     |
| 151         | 98              | 01/09/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 87     |
| 152         | 98              | 01/09/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 87     |



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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 153         | 98              | 01/09/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 88     |
| 154         | 113             | 01/24/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 89     |
| 155         | 113             | 01/24/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 90     |
| 156         | 116             | 01/27/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 91     |
| 157         | 116             | 01/27/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 91     |
| 158         | 116             | 01/27/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 92     |
| 159         | 116             | 01/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 93     |
| 160         | 116             | 01/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 93     |
| 161         | 135             | 02/15/2012                     |                | Dx        | 6929             |     | Grppract           | 1     | Contact Dermatitis Uns Cause         |                             |             |     |                              | TEDN   | 100    |
| 162         | 135             | 02/15/2012                     |                | Dx        | 79029            |     | Grppract           | 2     | Other Abnormal Glucose               |                             |             |     |                              | TEDN   | 100    |
| 163         | 135             | 02/15/2012                     |                | Dx        | 27800            |     | Grppract           | 3     | Obesity Unspecified                  |                             |             |     |                              | TEDN   | 100    |
| 164         | 135             | 02/15/2012                     |                | Dx        | 2449             |     | Grppract           | 4     | Uns Hypothyroidism                   |                             |             |     |                              | TEDN   | 100    |
| 165         | 135             | 02/15/2012                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes   |                             |             |     |                              | TEDN   | 100    |
| 166         | 135             | 02/15/2012                     |                | Rx        | 00186504031      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 94     |
| 167         | 135             | 02/15/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 95     |
| 168         | 135             | 02/15/2012                     |                | Rx        | 00115981101      |     |                    |       |                                      | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 96     |
| 169         | 135             | 02/15/2012                     |                | Rx        | 68645013154      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 97     |
| 170         | 135             | 02/15/2012                     |                | Rx        | 00168025846      |     |                    |       |                                      | Clotrimazole-Betamethasone  | 10          | 45  | Cream (Grams)                | PDTS   | 98     |
| 171         | 135             | 02/15/2012                     |                | Rx        | 00781709004      |     |                    |       |                                      | Ketoconazole                | 10          | 240 | Shampoo                      | PDTS   | 99     |
| 172         | 137             | 02/17/2012                     |                | Rx        | 00185034101      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 101    |
| 173         | 147             | 02/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 102    |
| 174         | 147             | 02/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 102    |
| 175         | 161             | 03/12/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 103    |
| 176         | 170             | 03/21/2012                     |                | Rx        | 00378180301      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 104    |
| 177         | 172             | 03/23/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 105    |
| 178         | 172             | 03/23/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 105    |
| 179         | 172             | 03/23/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 105    |
| 180         | 172             | 03/23/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 106    |
| 181         | 176             | 03/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 107    |
| 182         | 176             | 03/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 107    |
| 183         | 200             | 04/20/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 108    |
| 184         | 200             | 04/20/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 108    |
| 185         | 200             | 04/20/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 108    |
| 186         | 200             | 04/20/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 109    |
| 187         | 207             | 04/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 110    |
| 188         | 207             | 04/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 110    |
| 189         | 208             | 04/28/2012                     |                | Rx        | 68382005601      |     |                    |       |                                      | Warfarin Sodium             | 30          | 30  | Tablet                       | PDTS   | 111    |
| 190         | 231             | 05/21/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 112    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------------------|--------|--------|
| 191         | 231             | 05/21/2012                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                        |             |     |                              | TEDN   | 112    |
| 192         | 231             | 05/21/2012                     |                | Px        | 93000            |     | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds W/I&r      |                        |             |     |                              | TEDN   | 112    |
| 193         | 231             | 05/21/2012                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                        |             |     |                              | TEDN   | 113    |
| 194         | 233             | 05/23/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 114    |
| 195         | 233             | 05/23/2012                     |                | Rx        | 68645013154      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 115    |
| 196         | 233             | 05/23/2012                     |                | Rx        | 00186504031      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 116    |
| 197         | 233             | 05/23/2012                     |                | Rx        | 00115981101      |     |                    |       |                                           | Digoxin                | 90          | 90  | Tablet                       | PDTS   | 117    |
| 198         | 237             | 05/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 118    |
| 199         | 237             | 05/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 118    |
| 200         | 254             | 06/13/2012                     |                | Rx        | 68382005601      |     |                    |       |                                           | Warfarin Sodium        | 30          | 30  | Tablet                       | PDTS   | 119    |
| 201         | 254             | 06/13/2012                     |                | Rx        | 00378180301      |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                       | PDTS   | 120    |
| 202         | 259             | 06/18/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                              | TEDN   | 121    |
| 203         | 259             | 06/18/2012                     |                | Dx        | 42731            |     | Cardvasc           | 2     | Atrial Fibrillation                       |                        |             |     |                              | TEDN   | 121    |
| 204         | 259             | 06/18/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 121    |
| 205         | 259             | 06/18/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 122    |
| 206         | 268             | 06/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 123    |
| 207         | 268             | 06/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 123    |
| 208         | 276             | 07/05/2012                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other          |                        |             |     |                              | TEDN   | 124    |
| 209         | 276             | 07/05/2012                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilal Rspse Spmtry Pre&post-Brncdilal |                        |             |     |                              | TEDN   | 124    |
| 210         | 276             | 07/05/2012                     |                | Px        | 99205            |     | Pulmo              | 1     | Office Outpatient New 60 Minutes          |                        |             |     |                              | TEDN   | 125    |
| 211         | 277             | 07/06/2012                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium        | 84          | 54  | Tablet                       | PDTS   | 126    |
| 212         | 293             | 07/22/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                       | PDTS   | 127    |
| 213         | 293             | 07/22/2012                     |                | Rx        | 50111064702      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 128    |
| 214         | 293             | 07/22/2012                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 129    |
| 215         | 293             | 07/22/2012                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                | 90          | 90  | Tablet                       | PDTS   | 130    |
| 216         | 295             | 07/24/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 30          |     | REFILL                       | PDTS   | 131    |
| 217         | 298             | 07/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                              | TEDN   | 132    |
| 218         | 298             | 07/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                              | TEDN   | 132    |
| 219         | 304             | 08/02/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                        |             |     |                              | TEDN   | 133    |
| 220         | 304             | 08/02/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                        |             |     |                              | TEDN   | 133    |
| 221         | 304             | 08/02/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                        |             |     |                              | TEDN   | 134    |
| 222         | 304             | 08/02/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                           |                        |             |     |                              | TEDN   | 135    |
| 223         | 304             | 08/02/2012                     |                | Px        | 36600            |     | Pulmo              | 1     | Arterial Puncture Withdrawal Blood Dx     |                        |             |     |                              | TEDN   | 135    |
| 224         | 304             | 08/02/2012                     |                | Px        | 82375            |     | Pulmo              | 1     | Carboxyhemoglobin Quantitative            |                        |             |     |                              | TEDN   | 136    |
| 225         | 304             | 08/02/2012                     |                | Px        | 82803            |     | Pulmo              | 1     | Blood Gases Any Combination Ph Pco2 Po2 C |                        |             |     |                              | TEDN   | 137    |
| 226         | 304             | 08/02/2012                     |                | Px        | 85018            |     | Pulmo              | 1     | Blood Count Hemoglobin                    |                        |             |     |                              | TEDN   | 138    |
| 227         | 304             | 08/02/2012                     |                | Px        | 71250            |     | Pulmo              | 1     | Ct Thorax W/O Contrast Material           |                        |             |     |                              | TEDN   | 139    |
| 228         | 304             | 08/02/2012                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilal Rspse Spmtry Pre&post-Brncdilal |                        |             |     |                              | TEDN   | 140    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 229         | 304             | 08/02/2012                     |                | Px        | 94200            |     | Pulmo              | 1     | Max Breathing Capacity Maximal Voluntary  |                             |             |     |                              | TEDN   | 141    |
| 230         | 304             | 08/02/2012                     |                | Px        | 94726            |     | Pulmo              | 1     | Plethysmography Lung Volumes W/Wo Airway  |                             |             |     |                              | TEDN   | 142    |
| 231         | 304             | 08/02/2012                     |                | Px        | 94729            |     | Pulmo              | 1     | Diffusing Capacity                        |                             |             |     |                              | TEDN   | 143    |
| 232         | 304             | 08/02/2012                     |                | Dx        | 79319            |     | Grpprac            | 1     | Abnormal Findings Lung Field Other        |                             |             |     |                              | TEDN   | 144    |
| 233         | 304             | 08/02/2012                     |                | Px        | 71250            |     | Grpprac            | 1     | Ct Thorax W/O Contrast Material           |                             |             |     |                              | TEDN   | 144    |
| 234         | 314             | 08/12/2012                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 145    |
| 235         | 317             | 08/15/2012                     |                | Dx        | 79029            |     | Fp                 | 1     | Other Abnormal Glucose                    |                             |             |     |                              | TEDN   | 147    |
| 236         | 317             | 08/15/2012                     |                | Dx        | 2449             |     | Fp                 | 2     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 147    |
| 237         | 317             | 08/15/2012                     |                | Dx        | 71690            |     | Fp                 | 3     | Uns Arthropathy Site Uns                  |                             |             |     |                              | TEDN   | 147    |
| 238         | 317             | 08/15/2012                     |                | Dx        | 27800            |     | Fp                 | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 147    |
| 239         | 317             | 08/15/2012                     |                | Px        | 99213            |     | Fp                 | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                              | TEDN   | 147    |
| 240         | 317             | 08/15/2012                     |                | Dx        | 79029            |     | Grpprac            | 1     | Other Abnormal Glucose                    |                             |             |     |                              | TEDN   | 148    |
| 241         | 317             | 08/15/2012                     |                | Dx        | 2449             |     | Grpprac            | 2     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 148    |
| 242         | 317             | 08/15/2012                     |                | Dx        | 71690            |     | Grpprac            | 3     | Uns Arthropathy Site Uns                  |                             |             |     |                              | TEDN   | 148    |
| 243         | 317             | 08/15/2012                     |                | Dx        | 27800            |     | Grpprac            | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 148    |
| 244         | 317             | 08/15/2012                     |                | Px        | 99499            |     | Grpprac            | 1     | Unlisted Evaluation And Management Servic |                             |             |     |                              | TEDN   | 148    |
| 245         | 317             | 08/15/2012                     |                | Rx        | 65162061710      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 2           | 10  | Tablet                       | PDTS   | 146    |
| 246         | 322             | 08/20/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                           |                             |             |     |                              | TEDN   | 151    |
| 247         | 322             | 08/20/2012                     |                | Dx        | 32723            |     | Pulmo              | 2     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 151    |
| 248         | 322             | 08/20/2012                     |                | Dx        | 4770             |     | Pulmo              | 3     | Allergic Rhinitis Pollen                  |                             |             |     |                              | TEDN   | 151    |
| 249         | 322             | 08/20/2012                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 151    |
| 250         | 322             | 08/20/2012                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 149    |
| 251         | 322             | 08/20/2012                     |                | Rx        | 00597001314      |     |                    |       |                                           | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 150    |
| 252         | 323             | 08/21/2012                     |                | Rx        | 45802046564      |     |                    |       |                                           | Ketoconazole                | 90          | 240 | Shampoo                      | PDTS   | 152    |
| 253         | 328             | 08/26/2012                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 153    |
| 254         | 329             | 08/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 155    |
| 255         | 329             | 08/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 155    |
| 256         | 329             | 08/27/2012                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 154    |
| 257         | 347             | 09/14/2012                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 156    |
| 258         | 353             | 09/20/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 158    |
| 259         | 353             | 09/20/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 158    |
| 260         | 353             | 09/20/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 159    |
| 261         | 353             | 09/20/2012                     |                | Rx        | 50111064702      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 157    |
| 262         | 360             | 09/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 160    |
| 263         | 360             | 09/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 160    |
| 264         | 369             | 10/06/2012                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 161    |
| 265         | 369             | 10/06/2012                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 162    |
| 266         | 369             | 10/06/2012                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                     | 90          | 90  | Tablet                       | PDTS   | 163    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|--------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 267         | 374             | 10/11/2012                     |                | Rx        | 00781518110      |     |                    |       |                                      | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 164    |
| 268         | 381             | 10/18/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 165    |
| 269         | 381             | 10/18/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 165    |
| 270         | 381             | 10/18/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 166    |
| 271         | 390             | 10/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 167    |
| 272         | 390             | 10/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 167    |
| 273         | 397             | 11/03/2012                     |                | Rx        | 49884030402      |     |                    |       |                                      | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 168    |
| 274         | 397             | 11/03/2012                     |                | Rx        | 00597001314      |     |                    |       |                                      | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 169    |
| 275         | 399             | 11/05/2012                     |                | Dx        | 4928             |     | Pulmo              | 1     | Other Emphysema                      |                             |             |     |                              | TEDN   | 171    |
| 276         | 399             | 11/05/2012                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes   |                             |             |     |                              | TEDN   | 171    |
| 277         | 399             | 11/05/2012                     |                | Rx        | 00173069600      |     |                    |       |                                      | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 170    |
| 278         | 401             | 11/07/2012                     |                | Rx        | 45802046564      |     |                    |       |                                      | Ketoconazole                | 90          | 240 | Shampoo                      | PDTS   | 172    |
| 279         | 403             | 11/09/2012                     |                | Rx        | 59762525004      |     |                    |       |                                      | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 173    |
| 280         | 421             | 11/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 174    |
| 281         | 421             | 11/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 174    |
| 282         | 424             | 11/30/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 175    |
| 283         | 424             | 11/30/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 175    |
| 284         | 424             | 11/30/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 176    |
| 285         | 426             | 12/02/2012                     |                | Rx        | 50111064702      |     |                    |       |                                      | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 177    |
| 286         | 430             | 12/06/2012                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                  |                             |             |     |                              | TEDN   | 178    |
| 287         | 430             | 12/06/2012                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis   |                             |             |     |                              | TEDN   | 178    |
| 288         | 430             | 12/06/2012                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes   |                             |             |     |                              | TEDN   | 178    |
| 289         | 431             | 12/07/2012                     |                | Rx        | 60429078910      |     |                    |       |                                      | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 179    |
| 290         | 451             | 12/27/2012                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 180    |
| 291         | 451             | 12/27/2012                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 180    |
| 292         | 455             | 12/31/2012                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 181    |
| 293         | 455             | 12/31/2012                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                     |                             |             |     |                              | TEDN   | 181    |
| 294         | 455             | 12/31/2012                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes    |                             |             |     |                              | TEDN   | 182    |
| 295         | 459             | 01/04/2013                     |                | Rx        | 00173024275      |     |                    |       |                                      | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 183    |
| 296         | 459             | 01/04/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                      | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 184    |
| 297         | 459             | 01/04/2013                     |                | Rx        | 00186504085      |     |                    |       |                                      | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 185    |
| 298         | 465             | 01/10/2013                     |                | Rx        | 00172635960      |     |                    |       |                                      | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 186    |
| 299         | 473             | 01/18/2013                     |                | Rx        | 00173069600      |     |                    |       |                                      | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 187    |
| 300         | 482             | 01/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea              |                             |             |     |                              | TEDN   | 188    |
| 301         | 482             | 01/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                  |                             |             |     |                              | TEDN   | 188    |
| 302         | 487             | 02/01/2013                     |                | Rx        | 00597001314      |     |                    |       |                                      | Combivent                   | 90          | 59  | Aerosol W/Adapter (Gm)       | PDTS   | 189    |
| 303         | 487             | 02/01/2013                     |                | Rx        | 49884030402      |     |                    |       |                                      | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 190    |
| 304         | 490             | 02/04/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant    |                             |             |     |                              | TEDN   | 191    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 305         | 490             | 02/04/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 191    |
| 306         | 490             | 02/04/2013                     |                | Px        | 99211            |     | Cardvasc           | 1     | Office Outpatient Visit 5 Minutes         |                             |             |     |                              | TEDN   | 192    |
| 307         | 506             | 02/20/2013                     |                | Dx        | 2449             |     | Grppract           | 1     | Uns Hypothyroidism                        |                             |             |     |                              | TEDN   | 195    |
| 308         | 506             | 02/20/2013                     |                | Dx        | 4011             |     | Grppract           | 2     | Benign Essential Hypertension             |                             |             |     |                              | TEDN   | 195    |
| 309         | 506             | 02/20/2013                     |                | Dx        | 53081            |     | Grppract           | 3     | Esophageal Reflux                         |                             |             |     |                              | TEDN   | 195    |
| 310         | 506             | 02/20/2013                     |                | Dx        | 27800            |     | Grppract           | 4     | Obesity Unspecified                       |                             |             |     |                              | TEDN   | 195    |
| 311         | 506             | 02/20/2013                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                              | TEDN   | 195    |
| 312         | 506             | 02/20/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 193    |
| 313         | 506             | 02/20/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 194    |
| 314         | 513             | 02/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 196    |
| 315         | 513             | 02/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 196    |
| 316         | 515             | 03/01/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium             | 84          | 54  | Tablet                       | PDTS   | 197    |
| 317         | 519             | 03/05/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 198    |
| 318         | 522             | 03/08/2013                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 199    |
| 319         | 532             | 03/18/2013                     |                | Rx        | 00173024275      |     |                    |       |                                           | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 200    |
| 320         | 536             | 03/22/2013                     |                | Rx        | 45802005505      |     |                    |       |                                           | Triamcinolone Acetonide     | 14          | 454 | Ointment(Gm)                 | PDTS   | 201    |
| 321         | 538             | 03/24/2013                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 90          | 270 | Tablet                       | PDTS   | 202    |
| 322         | 541             | 03/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 203    |
| 323         | 541             | 03/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 203    |
| 324         | 549             | 04/04/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                       | PDTS   | 204    |
| 325         | 553             | 04/08/2013                     |                | Dx        | 79380            |     | Fp                 | 1     | Unsp Abnormal Mammogram                   |                             |             |     |                              | TEDN   | 205    |
| 326         | 553             | 04/08/2013                     |                | Px        | 76645            |     | Fp                 | 1     | Us Breast Real Time W/Image Documentation |                             |             |     |                              | TEDN   | 205    |
| 327         | 553             | 04/08/2013                     |                | Px        | 77051            |     | Fp                 | 1     | Computer-Aided Detection Dx Mammography   |                             |             |     |                              | TEDN   | 206    |
| 328         | 553             | 04/08/2013                     |                | Px        | G0206            |     | Fp                 | 1     | Diagnosticmammographydigital              |                             |             |     |                              | TEDN   | 207    |
| 329         | 563             | 04/18/2013                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 208    |
| 330         | 567             | 04/22/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                             |             |     |                              | TEDN   | 209    |
| 331         | 567             | 04/22/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                             |             |     |                              | TEDN   | 209    |
| 332         | 567             | 04/22/2013                     |                | Dx        | 70211            |     | Derm               | 1     | Inflamed Seborrheic Keratosis             |                             |             |     |                              | TEDN   | 210    |
| 333         | 567             | 04/22/2013                     |                | Px        | 11312            |     | Derm               | 1     | Shvg Skin Lesion 1 F/E/E/N/L/M Diam 1.1-2 |                             |             |     |                              | TEDN   | 210    |
| 334         | 572             | 04/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 211    |
| 335         | 572             | 04/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 211    |
| 336         | 577             | 05/02/2013                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 212    |
| 337         | 580             | 05/05/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                       | PDTS   | 213    |
| 338         | 580             | 05/05/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 214    |
| 339         | 592             | 05/17/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 215    |
| 340         | 600             | 05/25/2013                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 216    |
| 341         | 602             | 05/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                              | TEDN   | 217    |
| 342         | 602             | 05/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                              | TEDN   | 217    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|----------------------------|-------------|-----|------------------------------|--------|--------|
| 343         | 611             | 06/05/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                            |             |     |                              | TEDN   | 218    |
| 344         | 611             | 06/05/2013                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                            |             |     |                              | TEDN   | 218    |
| 345         | 611             | 06/05/2013                     |                | Dx        | 42731            |     | Cardvasc           | 3     | Atrial Fibrillation                       |                            |             |     |                              | TEDN   | 218    |
| 346         | 611             | 06/05/2013                     |                | Px        | 85610            |     | Cardvasc           | 1     | Prothrombin Time                          |                            |             |     |                              | TEDN   | 218    |
| 347         | 611             | 06/05/2013                     |                | Dx        | 94400            |     | Derm               | 1     | Burn Unsp Of Hand Unspec                  |                            |             |     |                              | TEDN   | 219    |
| 348         | 611             | 06/05/2013                     |                | Dx        | 6959             |     | Derm               | 2     | Uns Erythematous Condition                |                            |             |     |                              | TEDN   | 219    |
| 349         | 611             | 06/05/2013                     |                | Px        | 11100            |     | Derm               | 1     | Bx Skin Subcutaneous&/Mucous Membrane 1 L |                            |             |     |                              | TEDN   | 219    |
| 350         | 611             | 06/05/2013                     |                | Px        | 11101            |     | Derm               | 1     | Biopsy Skin Subq&/Mucous Membrane Ea Addl |                            |             |     |                              | TEDN   | 220    |
| 351         | 611             | 06/05/2013                     |                | Px        | 99213            |     | Derm               | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                              | TEDN   | 221    |
| 352         | 613             | 06/07/2013                     |                | Dx        | V5861            |     | Cardvasc           | 1     | Encounter Long Term Anticoagulant         |                            |             |     |                              | TEDN   | 222    |
| 353         | 613             | 06/07/2013                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                            |             |     |                              | TEDN   | 222    |
| 354         | 613             | 06/07/2013                     |                | Dx        | 42731            |     | Cardvasc           | 3     | Atrial Fibrillation                       |                            |             |     |                              | TEDN   | 222    |
| 355         | 613             | 06/07/2013                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                            |             |     |                              | TEDN   | 222    |
| 356         | 618             | 06/12/2013                     |                | Rx        | 00168016330      |     |                    |       |                                           | Clobetasol Propionate      | 30          | 60  | Cream (Grams)                | PDTS   | 223    |
| 357         | 618             | 06/12/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium            | 90          | 65  | Tablet                       | PDTS   | 224    |
| 358         | 633             | 06/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 225    |
| 359         | 633             | 06/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 225    |
| 360         | 646             | 07/10/2013                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                             |                            |             |     |                              | TEDN   | 227    |
| 361         | 646             | 07/10/2013                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes        |                            |             |     |                              | TEDN   | 227    |
| 362         | 646             | 07/10/2013                     |                | Rx        | 45802005505      |     |                    |       |                                           | Triamcinolone Acetonide    | 90          | 453 | Ointment(Gm)                 | PDTS   | 226    |
| 363         | 647             | 07/11/2013                     |                | Rx        | 60429090230      |     |                    |       |                                           | Clobetasol Propionate      | 30          | 60  | Cream (Grams)                | PDTS   | 228    |
| 364         | 651             | 07/15/2013                     |                | Rx        | 45802046564      |     |                    |       |                                           | Ketoconazole               | 30          | 240 | Shampoo                      | PDTS   | 229    |
| 365         | 651             | 07/15/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG           | 90          |     | REFILL                       | PDTS   | 230    |
| 366         | 651             | 07/15/2013                     |                | Rx        | 00172635960      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen | 90          | 270 | Tablet                       | PDTS   | 231    |
| 367         | 651             | 07/15/2013                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                | 90          | 180 | Tablet                       | PDTS   | 232    |
| 368         | 653             | 07/17/2013                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus              | 90          | 180 | Disk, With Inhalation Device | PDTS   | 233    |
| 369         | 660             | 07/24/2013                     |                | Rx        | 00115981103      |     |                    |       |                                           | Digoxin                    | 90          | 90  | Tablet                       | PDTS   | 234    |
| 370         | 663             | 07/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 235    |
| 371         | 663             | 07/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 235    |
| 372         | 666             | 07/30/2013                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other          |                            |             |     |                              | TEDN   | 236    |
| 373         | 666             | 07/30/2013                     |                | Dx        | 32723            |     | Pulmo              | 2     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 236    |
| 374         | 666             | 07/30/2013                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes        |                            |             |     |                              | TEDN   | 236    |
| 375         | 670             | 08/03/2013                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl             | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 237    |
| 376         | 670             | 08/03/2013                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium       | 90          | 90  | Tablet                       | PDTS   | 238    |
| 377         | 681             | 08/14/2013                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                     | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 239    |
| 378         | 692             | 08/25/2013                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium            | 90          | 65  | Tablet                       | PDTS   | 240    |
| 379         | 694             | 08/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                            |             |     |                              | TEDN   | 241    |
| 380         | 694             | 08/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                            |             |     |                              | TEDN   | 241    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-----------------------------------------|-----------------------------|-------------|-----|------------------------------|--------|--------|
| 381         | 703             | 09/05/2013                     |                | Dx        | 4019             |     | Grpract            | 1     | Unspecified Essential Hypertension      |                             |             |     |                              | TEDN   | 242    |
| 382         | 703             | 09/05/2013                     |                | Dx        | 4280             |     | Grpract            | 2     | Congestive Heart Failure Unspec         |                             |             |     |                              | TEDN   | 242    |
| 383         | 703             | 09/05/2013                     |                | Dx        | 2449             |     | Grpract            | 3     | Uns Hypothyroidism                      |                             |             |     |                              | TEDN   | 242    |
| 384         | 703             | 09/05/2013                     |                | Dx        | 53081            |     | Grpract            | 4     | Esophageal Reflux                       |                             |             |     |                              | TEDN   | 242    |
| 385         | 703             | 09/05/2013                     |                | Px        | 99214            |     | Grpract            | 1     | Office Outpatient Visit 25 Minutes      |                             |             |     |                              | TEDN   | 242    |
| 386         | 706             | 09/08/2013                     |                | Rx        | 45802005505      |     |                    |       |                                         | Triamcinolone Acetonide     | 90          | 454 | Ointment(Gm)                 | PDTS   | 243    |
| 387         | 711             | 09/13/2013                     |                | Rx        | 00172635960      |     |                    |       |                                         | Tramadol Hcl-Acetaminophen  | 23          | 90  | Tablet                       | PDTS   | 244    |
| 388         | 711             | 09/13/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                         | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 245    |
| 389         | 712             | 09/14/2013                     |                | Rx        | 49884030402      |     |                    |       |                                         | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 246    |
| 390         | 713             | 09/15/2013                     |                | Rx        | 00173069600      |     |                    |       |                                         | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 247    |
| 391         | 721             | 09/23/2013                     |                | Rx        | 24987024257      |     |                    |       |                                         | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 248    |
| 392         | 725             | 09/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 249    |
| 393         | 725             | 09/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 249    |
| 394         | 726             | 09/28/2013                     |                | Rx        | 45802046564      |     |                    |       |                                         | Ketoconazole                | 30          | 240 | Shampoo                      | PDTS   | 250    |
| 395         | 726             | 09/28/2013                     |                | Rx        | 59762525004      |     |                    |       |                                         | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 251    |
| 396         | 726             | 09/28/2013                     |                | Rx        | 60429090260      |     |                    |       |                                         | Clobetasol Propionate       | 30          | 60  | Cream (Grams)                | PDTS   | 252    |
| 397         | 732             | 10/04/2013                     |                | Rx        | 00781282310      |     |                    |       |                                         | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)   | PDTS   | 253    |
| 398         | 732             | 10/04/2013                     |                | Rx        | 00074455219      |     |                    |       |                                         | Synthroid                   | 90          | 90  | Tablet                       | PDTS   | 254    |
| 399         | 737             | 10/09/2013                     |                | Dx        | V679             |     | Fp                 | 1     | Uns Follow-Up Examination               |                             |             |     |                              | TEDN   | 255    |
| 400         | 737             | 10/09/2013                     |                | Px        | 77051            |     | Fp                 | 1     | Computer-Aided Detection Dx Mammography |                             |             |     |                              | TEDN   | 255    |
| 401         | 737             | 10/09/2013                     |                | Px        | G0206            |     | Fp                 | 1     | Diagnosticmammographydigital            |                             |             |     |                              | TEDN   | 256    |
| 402         | 742             | 10/14/2013                     |                | Rx        | 00186504085      |     |                    |       |                                         | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated) | PDTS   | 257    |
| 403         | 755             | 10/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 258    |
| 404         | 755             | 10/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 258    |
| 405         | 764             | 11/05/2013                     |                | Rx        | 60429078910      |     |                    |       |                                         | Warfarin Sodium             | 90          | 65  | Tablet                       | PDTS   | 259    |
| 406         | 765             | 11/06/2013                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                           |                             |             |     |                              | TEDN   | 260    |
| 407         | 765             | 11/06/2013                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes      |                             |             |     |                              | TEDN   | 260    |
| 408         | 773             | 11/14/2013                     |                | Rx        | 49884030402      |     |                    |       |                                         | Zafirlukast                 | 90          | 180 | Tablet                       | PDTS   | 261    |
| 409         | 774             | 11/15/2013                     |                | Rx        | 00173069600      |     |                    |       |                                         | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device | PDTS   | 262    |
| 410         | 784             | 11/25/2013                     |                | Rx        | 24987024257      |     |                    |       |                                         | Lanoxin                     | 90          | 90  | Tablet                       | PDTS   | 263    |
| 411         | 786             | 11/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 265    |
| 412         | 786             | 11/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 265    |
| 413         | 786             | 11/27/2013                     |                | Rx        | 59762525004      |     |                    |       |                                         | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                       | PDTS   | 264    |
| 414         | 793             | 12/04/2013                     |                | Rx        | 00074455290      |     |                    |       |                                         | Synthroid                   | 90          | 90  | Tablet                       | PDTS   | 266    |
| 415         | 812             | 12/23/2013                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                         | INDEX STUDY DRUG            | 30          |     | REFILL                       | PDTS   | 267    |
| 416         | 816             | 12/27/2013                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                 |                             |             |     |                              | TEDN   | 268    |
| 417         | 816             | 12/27/2013                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                     |                             |             |     |                              | TEDN   | 268    |
| 418         | 825             | 01/05/2014                     |                | Rx        | 60429078910      |     |                    |       |                                         | Warfarin Sodium             | 90          | 65  | Tablet                       | PDTS   | 269    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|----------------------------------|--------|--------|
| 419         | 833             | 01/13/2014                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                                  | TEDN   | 271    |
| 420         | 833             | 01/13/2014                     |                | Dx        | 28659            |     | Cardvasc           | 2     | Ot Intrin Circ Anticoag Hemorr Dis        |                             |             |     |                                  | TEDN   | 271    |
| 421         | 833             | 01/13/2014                     |                | Dx        | 4011             |     | Cardvasc           | 3     | Benign Essential Hypertension             |                             |             |     |                                  | TEDN   | 271    |
| 422         | 833             | 01/13/2014                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 271    |
| 423         | 833             | 01/13/2014                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 270    |
| 424         | 834             | 01/14/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                           | PDTS   | 272    |
| 425         | 835             | 01/15/2014                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus               | 90          | 180 | Disk, With Inhalation Device     | PDTS   | 273    |
| 426         | 841             | 01/21/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 30          |     | REFILL                           | PDTS   | 274    |
| 427         | 843             | 01/23/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 275    |
| 428         | 847             | 01/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                                  | TEDN   | 277    |
| 429         | 847             | 01/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                                  | TEDN   | 277    |
| 430         | 847             | 01/27/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                           | PDTS   | 276    |
| 431         | 854             | 02/03/2014                     |                | Dx        | 496              |     | Pulmo              | 1     | Chronic Airway Obstruction Other          |                             |             |     |                                  | TEDN   | 279    |
| 432         | 854             | 02/03/2014                     |                | Px        | 36600            |     | Pulmo              | 1     | Arterial Puncture Withdrawal Blood Dx     |                             |             |     |                                  | TEDN   | 279    |
| 433         | 854             | 02/03/2014                     |                | Px        | 82375            |     | Pulmo              | 1     | Carboxyhemoglobin Quantitative            |                             |             |     |                                  | TEDN   | 280    |
| 434         | 854             | 02/03/2014                     |                | Px        | 82803            |     | Pulmo              | 1     | Blood Gases Any Combination Ph Pco2 Po2 C |                             |             |     |                                  | TEDN   | 281    |
| 435         | 854             | 02/03/2014                     |                | Px        | 85018            |     | Pulmo              | 1     | Blood Count Hemoglobin                    |                             |             |     |                                  | TEDN   | 282    |
| 436         | 854             | 02/03/2014                     |                | Px        | 99214            |     | Pulmo              | 1     | Office Outpatient Visit 25 Minutes        |                             |             |     |                                  | TEDN   | 283    |
| 437         | 854             | 02/03/2014                     |                | Px        | 71250            |     | Pulmo              | 1     | Ct Thorax W/O Contrast Material           |                             |             |     |                                  | TEDN   | 284    |
| 438         | 854             | 02/03/2014                     |                | Px        | 94060            |     | Pulmo              | 1     | Brncdilal Rspse Spmtry Pre&post-Brncdilal |                             |             |     |                                  | TEDN   | 285    |
| 439         | 854             | 02/03/2014                     |                | Px        | 94200            |     | Pulmo              | 1     | Max Breathing Capacity Maximal Voluntary  |                             |             |     |                                  | TEDN   | 286    |
| 440         | 854             | 02/03/2014                     |                | Px        | 94726            |     | Pulmo              | 1     | Plethysmography Lung Volumes W/Wo Airway  |                             |             |     |                                  | TEDN   | 287    |
| 441         | 854             | 02/03/2014                     |                | Px        | 94729            |     | Pulmo              | 1     | Diffusing Capacity                        |                             |             |     |                                  | TEDN   | 288    |
| 442         | 854             | 02/03/2014                     |                | Dx        | 78605            |     | Grppract           | 1     | Shortness Breath                          |                             |             |     |                                  | TEDN   | 289    |
| 443         | 854             | 02/03/2014                     |                | Px        | 71250            |     | Grppract           | 1     | Ct Thorax W/O Contrast Material           |                             |             |     |                                  | TEDN   | 289    |
| 444         | 854             | 02/03/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 278    |
| 445         | 876             | 02/25/2014                     |                | Rx        | 59762525004      |     |                    |       |                                           | Fosinopril-Hydrochlorothiaz | 90          | 90  | Tablet                           | PDTS   | 290    |
| 446         | 878             | 02/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                             |             |     |                                  | TEDN   | 291    |
| 447         | 878             | 02/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                             |             |     |                                  | TEDN   | 291    |
| 448         | 882             | 03/03/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 292    |
| 449         | 884             | 03/05/2014                     |                | Dx        | 2449             |     | Grppract           | 1     | Uns Hypothyroidism                        |                             |             |     |                                  | TEDN   | 296    |
| 450         | 884             | 03/05/2014                     |                | Dx        | 27800            |     | Grppract           | 2     | Obesity Unspecified                       |                             |             |     |                                  | TEDN   | 296    |
| 451         | 884             | 03/05/2014                     |                | Dx        | 42731            |     | Grppract           | 3     | Atrial Fibrillation                       |                             |             |     |                                  | TEDN   | 296    |
| 452         | 884             | 03/05/2014                     |                | Dx        | 51631            |     | Grppract           | 4     | Idiopathic Pulmonary Fibrosis             |                             |             |     |                                  | TEDN   | 296    |
| 453         | 884             | 03/05/2014                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 296    |
| 454         | 884             | 03/05/2014                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                           | PDTS   | 293    |
| 455         | 884             | 03/05/2014                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 294    |
| 456         | 884             | 03/05/2014                     |                | Rx        | 65162062711      |     |                    |       |                                           | Tramadol Hcl                | 90          | 180 | Tablet                           | PDTS   | 295    |



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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|----------------------------------|--------|--------|
| 457         | 903             | 03/24/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 297    |
| 458         | 906             | 03/27/2014                     |                | Dx        | 32723            |     | Medic              | 1     | Obstructive Sleep Apnea                   |                        |             |     |                                  | TEDN   | 299    |
| 459         | 906             | 03/27/2014                     |                | Px        | E1390            |     | Medic              | 1     | Oxygen Concentrator                       |                        |             |     |                                  | TEDN   | 299    |
| 460         | 906             | 03/27/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast            | 90          | 180 | Tablet                           | PDTS   | 298    |
| 461         | 910             | 03/31/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                | 90          | 90  | Tablet                           | PDTS   | 300    |
| 462         | 910             | 03/31/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole           | 84          | 120 | Shampoo                          | PDTS   | 301    |
| 463         | 910             | 03/31/2014                     |                | Rx        | 50458065060      |     |                    |       |                                           | Ultracet               | 23          | 90  | Tablet                           | PDTS   | 302    |
| 464         | 919             | 04/09/2014                     |                | Dx        | 6961             |     | Derm               | 1     | Oth Psoriasis                             |                        |             |     |                                  | TEDN   | 303    |
| 465         | 919             | 04/09/2014                     |                | Px        | 99212            |     | Derm               | 1     | Office Outpatient Visit 10 Minutes        |                        |             |     |                                  | TEDN   | 303    |
| 466         | 925             | 04/15/2014                     |                | Rx        | 00173069600      |     |                    |       |                                           | Advair Diskus          | 90          | 180 | Disk, With Inhalation Device     | PDTS   | 304    |
| 467         | 936             | 04/26/2014                     |                | Rx        | 60429078910      |     |                    |       |                                           | Warfarin Sodium        | 90          | 65  | Tablet                           | PDTS   | 305    |
| 468         | 944             | 05/04/2014                     |                | Rx        | 00781282310      |     |                    |       |                                           | Fluoxetine Hcl         | 90          | 90  | Capsule (Hard, Soft, Etc.)       | PDTS   | 306    |
| 469         | 944             | 05/04/2014                     |                | Rx        | 00781518110      |     |                    |       |                                           | Levothyroxine Sodium   | 90          | 90  | Tablet                           | PDTS   | 307    |
| 470         | 963             | 05/23/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                 | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 308    |
| 471         | 964             | 05/24/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair       | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 309    |
| 472         | 964             | 05/24/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG       | 90          |     | REFILL                           | PDTS   | 310    |
| 473         | 966             | 05/26/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast            | 90          | 180 | Tablet                           | PDTS   | 311    |
| 474         | 968             | 05/28/2014                     |                | Rx        | 60429090260      |     |                    |       |                                           | Clobetasol Propionate  | 75          | 60  | Cream (Grams)                    | PDTS   | 312    |
| 475         | 991             | 06/20/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole           | 84          | 120 | Shampoo                          | PDTS   | 313    |
| 476         | 991             | 06/20/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                | 90          | 90  | Tablet                           | PDTS   | 314    |
| 477         | 1017            | 07/16/2014                     |                | Dx        | 78605            |     | Fp                 | 1     | Shortness Breath                          |                        |             |     |                                  | TEDN   | 316    |
| 478         | 1017            | 07/16/2014                     |                | Dx        | V5861            |     | Fp                 | 2     | Encounter Long Term Anticoagulant         |                        |             |     |                                  | TEDN   | 316    |
| 479         | 1017            | 07/16/2014                     |                | Px        | 71020            |     | Fp                 | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                  | TEDN   | 316    |
| 480         | 1017            | 07/16/2014                     |                | Px        | 85610            |     | Fp                 | 1     | Prothrombin Time                          |                        |             |     |                                  | TEDN   | 317    |
| 481         | 1017            | 07/16/2014                     |                | Px        | 99214            |     | Grppract           | 1     | Office Outpatient Visit 25 Minutes        |                        |             |     |                                  | TEDN   | 320    |
| 482         | 1017            | 07/16/2014                     |                | Px        | 99283            |     | Grppract           | 1     | Emergency Department Visit Moderate Sever |                        |             |     |                                  | TEDN   | 321    |
| 483         | 1017            | 07/16/2014                     |                | Px        | 71020            |     | Grppract           | 1     | Radiologic Exam Chest 2 Views Frontal&lat |                        |             |     |                                  | TEDN   | 322    |
| 484         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 5781             |     |                    |       | 1 Blood In Stool                          |                        |             |     |                                  | TEDI   | 323    |
| 485         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 2800             |     |                    |       | 2 Iron Deficiency Anemia Blood Loss       |                        |             |     |                                  | TEDI   | 323    |
| 486         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 42731            |     |                    |       | 3 Atrial Fibrillation                     |                        |             |     |                                  | TEDI   | 323    |
| 487         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 79431            |     |                    |       | 4 Abnorm Electrocardiogram                |                        |             |     |                                  | TEDI   | 323    |
| 488         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 515              |     |                    |       | 5 Postinflammatory Pulmonary Fibrosis     |                        |             |     |                                  | TEDI   | 323    |
| 489         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 71590            |     |                    |       | 6 Osteoarthritis Unsp Site                |                        |             |     |                                  | TEDI   | 323    |
| 490         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 2449             |     |                    |       | 7 Uns Hypothyroidism                      |                        |             |     |                                  | TEDI   | 323    |
| 491         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | 30000            |     |                    |       | 8 Anxiety State Unspecified               |                        |             |     |                                  | TEDI   | 323    |
| 492         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | V5861            |     |                    |       | 9 Encounter Long Term Anticoagulant       |                        |             |     |                                  | TEDI   | 323    |
| 493         | 1017            | 07/16/2014                     | 07/19/2014     | Dx        | V4586            |     |                    |       | 10 Bariatric Surgery Status               |                        |             |     |                                  | TEDI   | 323    |
| 494         | 1017            | 07/16/2014                     | 07/19/2014     | Px        | 4513             |     |                    |       | 1 Sm Bowel Endoscopy Other Spec           |                        |             |     |                                  | TEDI   | 323    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------|------|--------------------|-------|-------------------------------------------|------------------------|-------------|-----|------------------|--------|--------|
| 495         | 1017            | 07/16/2014                     | 07/19/2014     | Px        | 9904  |      |                    | 2     | Transfusion Of Packed Cells               |                        |             |     |                  | TEDI   | 323    |
| 496         | 1017            | 07/16/2014                     |                | Dx        | 79431 | Inpt | Cardvasc           | 1     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 315    |
| 497         | 1017            | 07/16/2014                     |                | Px        | 93010 | Inpt | Cardvasc           | 1     | Ecg Routine Ecg W/Least 12 Lds I&r Only   |                        |             |     |                  | TEDN   | 315    |
| 498         | 1017            | 07/16/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 318    |
| 499         | 1017            | 07/16/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 318    |
| 500         | 1017            | 07/16/2014                     |                | Px        | 99221 | Inpt | Gastro             | 1     | Initial Hospital Care/Day 30 Minutes      |                        |             |     |                  | TEDN   | 318    |
| 501         | 1017            | 07/16/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 319    |
| 502         | 1017            | 07/16/2014                     |                | Dx        | 2800  | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                        |             |     |                  | TEDN   | 319    |
| 503         | 1017            | 07/16/2014                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 319    |
| 504         | 1017            | 07/16/2014                     |                | Dx        | 79431 | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 319    |
| 505         | 1017            | 07/16/2014                     |                | Dx        | 515   | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                        |             |     |                  | TEDN   | 319    |
| 506         | 1017            | 07/16/2014                     |                | Dx        | 71590 | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                        |             |     |                  | TEDN   | 319    |
| 507         | 1017            | 07/16/2014                     |                | Dx        | 2449  | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 319    |
| 508         | 1017            | 07/16/2014                     |                | Dx        | 30000 | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                        |             |     |                  | TEDN   | 319    |
| 509         | 1017            | 07/16/2014                     |                | Px        | 99222 | Inpt | Grppract           | 1     | Initial Hospital Care/Day 50 Minutes      |                        |             |     |                  | TEDN   | 319    |
| 510         | 1018            | 07/17/2014                     |                | Dx        | 78605 | Inpt | Cardvasc           | 1     | Shortness Breath                          |                        |             |     |                  | TEDN   | 324    |
| 511         | 1018            | 07/17/2014                     |                | Dx        | 79431 | Inpt | Cardvasc           | 2     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 324    |
| 512         | 1018            | 07/17/2014                     |                | Px        | 93306 | Inpt | Cardvasc           | 1     | Echo Tthrc R-T 2d W/Wom-Mode Compl Spec&c |                        |             |     |                  | TEDN   | 324    |
| 513         | 1018            | 07/17/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 325    |
| 514         | 1018            | 07/17/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 325    |
| 515         | 1018            | 07/17/2014                     |                | Px        | 43235 | Inpt | Gastro             | 1     | Upper Gi Ndsc Dx W/Wo Collection Specimen |                        |             |     |                  | TEDN   | 325    |
| 516         | 1018            | 07/17/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 326    |
| 517         | 1018            | 07/17/2014                     |                | Dx        | 2800  | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                        |             |     |                  | TEDN   | 326    |
| 518         | 1018            | 07/17/2014                     |                | Dx        | 42731 | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 326    |
| 519         | 1018            | 07/17/2014                     |                | Dx        | 79431 | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                        |             |     |                  | TEDN   | 326    |
| 520         | 1018            | 07/17/2014                     |                | Dx        | 515   | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                        |             |     |                  | TEDN   | 326    |
| 521         | 1018            | 07/17/2014                     |                | Dx        | 71590 | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                        |             |     |                  | TEDN   | 326    |
| 522         | 1018            | 07/17/2014                     |                | Dx        | 2449  | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                        |             |     |                  | TEDN   | 326    |
| 523         | 1018            | 07/17/2014                     |                | Dx        | 30000 | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                        |             |     |                  | TEDN   | 326    |
| 524         | 1018            | 07/17/2014                     |                | Px        | 99232 | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 326    |
| 525         | 1018            | 07/17/2014                     |                | Px        | 74150 | Inpt | Grppract           | 1     | Ct Abdomen W/O Contrast Material          |                        |             |     |                  | TEDN   | 327    |
| 526         | 1019            | 07/18/2014                     |                | Dx        | 42731 | Inpt | Cardvasc           | 1     | Atrial Fibrillation                       |                        |             |     |                  | TEDN   | 328    |
| 527         | 1019            | 07/18/2014                     |                | Dx        | 5789  | Inpt | Cardvasc           | 2     | Uns Hemorr Gastrointestinal Tract         |                        |             |     |                  | TEDN   | 328    |
| 528         | 1019            | 07/18/2014                     |                | Px        | 99232 | Inpt | Cardvasc           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                        |             |     |                  | TEDN   | 328    |
| 529         | 1019            | 07/18/2014                     |                | Dx        | 5781  | Inpt | Gastro             | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 329    |
| 530         | 1019            | 07/18/2014                     |                | Dx        | V4586 | Inpt | Gastro             | 2     | Bariatric Surgery Status                  |                        |             |     |                  | TEDN   | 329    |
| 531         | 1019            | 07/18/2014                     |                | Px        | 99231 | Inpt | Gastro             | 1     | Sbsq Hospital Care/Day 15 Minutes         |                        |             |     |                  | TEDN   | 329    |
| 532         | 1019            | 07/18/2014                     |                | Dx        | 5781  | Inpt | Grppract           | 1     | Blood In Stool                            |                        |             |     |                  | TEDN   | 330    |

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|-------------|-----------------|--------------------------------|----------------|-----------|-------------|------|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|----------------------------|--------|--------|
| 533         | 1019            | 07/18/2014                     |                | Dx        | 2800        | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                             |             |     |                            | TEDN   | 330    |
| 534         | 1019            | 07/18/2014                     |                | Dx        | 42731       | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 330    |
| 535         | 1019            | 07/18/2014                     |                | Dx        | 79431       | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                             |             |     |                            | TEDN   | 330    |
| 536         | 1019            | 07/18/2014                     |                | Dx        | 515         | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                             |             |     |                            | TEDN   | 330    |
| 537         | 1019            | 07/18/2014                     |                | Dx        | 71590       | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                             |             |     |                            | TEDN   | 330    |
| 538         | 1019            | 07/18/2014                     |                | Dx        | 2449        | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                             |             |     |                            | TEDN   | 330    |
| 539         | 1019            | 07/18/2014                     |                | Dx        | 30000       | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                             |             |     |                            | TEDN   | 330    |
| 540         | 1019            | 07/18/2014                     |                | Px        | 99232       | Inpt | Grppract           | 1     | Sbsq Hospital Care/Day 25 Minutes         |                             |             |     |                            | TEDN   | 330    |
| 542         | 1020            | 07/19/2014                     |                | Dx        | 5781        | Inpt | Grppract           | 1     | Blood In Stool                            |                             |             |     |                            | TEDN   | 332    |
| 543         | 1020            | 07/19/2014                     |                | Dx        | 2800        | Inpt | Grppract           | 2     | Iron Deficiency Anemia Blood Loss         |                             |             |     |                            | TEDN   | 332    |
| 544         | 1020            | 07/19/2014                     |                | Dx        | 42731       | Inpt | Grppract           | 3     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 332    |
| 545         | 1020            | 07/19/2014                     |                | Dx        | 79431       | Inpt | Grppract           | 4     | Abnorm Electrocardiogram                  |                             |             |     |                            | TEDN   | 332    |
| 546         | 1020            | 07/19/2014                     |                | Dx        | 515         | Inpt | Grppract           | 5     | Postinflammatory Pulmonary Fibrosis       |                             |             |     |                            | TEDN   | 332    |
| 547         | 1020            | 07/19/2014                     |                | Dx        | 71590       | Inpt | Grppract           | 6     | Osteoarthritis Unsp Site                  |                             |             |     |                            | TEDN   | 332    |
| 548         | 1020            | 07/19/2014                     |                | Dx        | 2449        | Inpt | Grppract           | 7     | Uns Hypothyroidism                        |                             |             |     |                            | TEDN   | 332    |
| 549         | 1020            | 07/19/2014                     |                | Dx        | 30000       | Inpt | Grppract           | 8     | Anxiety State Unspecified                 |                             |             |     |                            | TEDN   | 332    |
| 550         | 1020            | 07/19/2014                     |                | Px        | 99238       | Inpt | Grppract           | 1     | Hospital Discharge Day Management 30 Min/ |                             |             |     |                            | TEDN   | 332    |
| 541         | 1020            | 07/19/2014                     |                | Rx        | 53746027205 |      |                    |       |                                           | Sulfamethoxazole-Trimethopr | 3           | 6   | Tablet                     | PDTS   | 331    |
| 551         | 1022            | 07/21/2014                     |                | Rx        | 00781518110 |      |                    |       |                                           | Levothyroxine Sodium        | 90          | 90  | Tablet                     | PDTS   | 333    |
| 552         | 1024            | 07/23/2014                     |                | Rx        | 60429090260 |      |                    |       |                                           | Clobetasol Propionate       | 90          | 60  | Cream (Grams)              | PDTS   | 334    |
| 553         | 1029            | 07/28/2014                     |                | Dx        | 2809        |      | Gastro             | 1     | Uns Iron Deficiency Anemia                |                             |             |     |                            | TEDN   | 335    |
| 554         | 1029            | 07/28/2014                     |                | Dx        | 5781        |      | Gastro             | 2     | Blood In Stool                            |                             |             |     |                            | TEDN   | 335    |
| 555         | 1029            | 07/28/2014                     |                | Px        | 99212       |      | Gastro             | 1     | Office Outpatient Visit 10 Minutes        |                             |             |     |                            | TEDN   | 335    |
| 556         | 1031            | 07/30/2014                     |                | Dx        | 4011        |      | Cardvasc           | 1     | Benign Essential Hypertension             |                             |             |     |                            | TEDN   | 336    |
| 557         | 1031            | 07/30/2014                     |                | Dx        | 42731       |      | Cardvasc           | 2     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 336    |
| 558         | 1031            | 07/30/2014                     |                | Dx        | 28659       |      | Cardvasc           | 3     | Ot Intrin Circ Anticoag Hemorr Dis        |                             |             |     |                            | TEDN   | 336    |
| 559         | 1031            | 07/30/2014                     |                | Px        | 99213       |      | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                            | TEDN   | 336    |
| 560         | 1034            | 08/02/2014                     |                | Rx        | 00781282310 |      |                    |       |                                           | Fluoxetine Hcl              | 90          | 90  | Capsule (Hard, Soft, Etc.) | PDTS   | 337    |
| 561         | 1037            | 08/05/2014                     |                | Dx        | 5789        |      | Grppract           | 1     | Uns Hemorr Gastrointestinal Tract         |                             |             |     |                            | TEDN   | 338    |
| 562         | 1037            | 08/05/2014                     |                | Dx        | 51889       |      | Grppract           | 2     | Oth Diseases Lung Other                   |                             |             |     |                            | TEDN   | 338    |
| 563         | 1037            | 08/05/2014                     |                | Dx        | 4279        |      | Grppract           | 3     | Uns Cardiac Dysrhythmia                   |                             |             |     |                            | TEDN   | 338    |
| 564         | 1037            | 08/05/2014                     |                | Dx        | 5990        |      | Grppract           | 4     | Urinary Tract Infection Unspec            |                             |             |     |                            | TEDN   | 338    |
| 565         | 1037            | 08/05/2014                     |                | Px        | 99213       |      | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                            | TEDN   | 338    |
| 566         | 1040            | 08/08/2014                     |                | Rx        | 47781030301 |      |                    |       |                                           | Nitrofurantoin Mono-Macro   | 7           | 14  | Capsule (Hard, Soft, Etc.) | PDTS   | 339    |
| 567         | 1043            | 08/11/2014                     |                | Dx        | 42731       |      | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                            | TEDN   | 340    |
| 568         | 1043            | 08/11/2014                     |                | Dx        | 78609       |      | Cardvasc           | 2     | Respiratory Abnormality Ot                |                             |             |     |                            | TEDN   | 340    |
| 569         | 1043            | 08/11/2014                     |                | Dx        | 4011        |      | Cardvasc           | 3     | Benign Essential Hypertension             |                             |             |     |                            | TEDN   | 340    |
| 570         | 1043            | 08/11/2014                     |                | Px        | 78452       |      | Cardvasc           | 1     | Myocardial Spect Multiple Studies         |                             |             |     |                            | TEDN   | 340    |

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|-------------|-----------------|--------------------------------|----------------|-----------|------------------|-----|--------------------|-------|-------------------------------------------|-----------------------------|-------------|-----|----------------------------------|--------|--------|
| 571         | 1043            | 08/11/2014                     |                | Px        | 93015            |     | Cardvasc           | 1     | Cv Strs Tst Xers&/Or Rx Cont Ecg Phys Si& |                             |             |     |                                  | TEDN   | 341    |
| 572         | 1043            | 08/11/2014                     |                | Px        | A9500            |     | Cardvasc           | 1     | Tc99m Sestamibi                           |                             |             |     |                                  | TEDN   | 342    |
| 573         | 1043            | 08/11/2014                     |                | Px        | J2785            |     | Cardvasc           | 1     | Regadenoson Injection                     |                             |             |     |                                  | TEDN   | 343    |
| 574         | 1046            | 08/14/2014                     |                | Rx        | 53746017801      |     |                    |       |                                           | Metformin Hcl Er            | 30          | 30  | Tablet, SR 24hr                  | PDTS   | 344    |
| 575         | 1050            | 08/18/2014                     |                | Rx        | 42291061010      |     |                    |       |                                           | Metformin Hcl Er            | 90          | 90  | Tablet, SR 24hr                  | PDTS   | 345    |
| 576         | 1053            | 08/21/2014                     |                | Rx        | 00186504085      |     |                    |       |                                           | Nexium                      | 90          | 90  | Capsule, DR (Enteric Coated)     | PDTS   | 346    |
| 577         | 1053            | 08/21/2014                     |                | Rx        | INDEX STUDY DRUG |     |                    |       |                                           | INDEX STUDY DRUG            | 90          |     | REFILL                           | PDTS   | 347    |
| 578         | 1056            | 08/24/2014                     |                | Rx        | 49884030402      |     |                    |       |                                           | Zafirlukast                 | 90          | 180 | Tablet                           | PDTS   | 348    |
| 579         | 1061            | 08/29/2014                     |                | Rx        | 00310014111      |     |                    |       |                                           | Zestoretic                  | 90          | 90  | Tablet                           | PDTS   | 349    |
| 580         | 1061            | 08/29/2014                     |                | Rx        | 68180051801      |     |                    |       |                                           | Lisinopril-Hydrochlorothiaz | 14          | 14  | Tablet                           | PDTS   | 350    |
| 581         | 1065            | 09/02/2014                     |                | Dx        | 79029            |     | Grppract           | 1     | Other Abnormal Glucose                    |                             |             |     |                                  | TEDN   | 352    |
| 582         | 1065            | 09/02/2014                     |                | Px        | 99213            |     | Grppract           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 352    |
| 583         | 1065            | 09/02/2014                     |                | Rx        | 53746061701      |     |                    |       |                                           | Tramadol Hcl-Acetaminophen  | 8           | 30  | Tablet                           | PDTS   | 351    |
| 584         | 1072            | 09/09/2014                     |                | Rx        | 50458065060      |     |                    |       |                                           | Ultracet                    | 90          | 360 | Tablet                           | PDTS   | 353    |
| 585         | 1075            | 09/12/2014                     |                | Rx        | 10147075004      |     |                    |       |                                           | Ketoconazole                | 84          | 120 | Shampoo                          | PDTS   | 354    |
| 586         | 1078            | 09/15/2014                     |                | Dx        | 42731            |     | Cardvasc           | 1     | Atrial Fibrillation                       |                             |             |     |                                  | TEDN   | 355    |
| 587         | 1078            | 09/15/2014                     |                | Dx        | 2859             |     | Cardvasc           | 2     | Anemia Unspecified                        |                             |             |     |                                  | TEDN   | 355    |
| 588         | 1078            | 09/15/2014                     |                | Px        | 99213            |     | Cardvasc           | 1     | Office Outpatient Visit 15 Minutes        |                             |             |     |                                  | TEDN   | 355    |
| 589         | 1079            | 09/16/2014                     |                | Rx        | 00456080060      |     |                    |       |                                           | Tudorza Pressair            | 30          | 1   | Aerosol Powder, Breath Activated | PDTS   | 356    |
| 590         | 1093            | 09/30/2014                     |                | Rx        | 24987024257      |     |                    |       |                                           | Lanoxin                     | 90          | 90  | Tablet                           | PDTS   | 357    |

End of Profile

### APPENDIX 3. STUDY DRUG COHORT DEFINITIONS

#### 1) **Dronedarone** – Multaq

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00024414210 | MULTAQ             |
| 00024414218 | MULTAQ             |
| 00024414250 | MULTAQ             |
| 00024414260 | MULTAQ             |
| 21695092060 | MULTAQ             |
| 53360414200 | MULTAQ             |
| 54868308600 | MULTAQ             |
| End         |                    |

2) **Amiodarone** – Cordarone, Cordarone IV, Pacerone

| <b>NDC</b>  | <b>DESCRIPTION</b>                 |
|-------------|------------------------------------|
| 00008081401 | CORDARONE IV                       |
| 00008418802 | CORDARONE                          |
| 00008418804 | CORDARONE                          |
| 00008418806 | CORDARONE                          |
| 00074434835 | AMIODARONE HCL                     |
| 00093913306 | AMIODARONE HCL                     |
| 00093913352 | AMIODARONE HCL                     |
| 00093913393 | AMIODARONE HCL                     |
| 00143987501 | AMIODARONE HCL INJECTION, SOLUTION |
| 00143987510 | AMIODARONE HYDROCHLORIDE           |
| 00185014405 | AMIODARONE HCL                     |
| 00185014409 | AMIODARONE HCL                     |
| 00185014460 | AMIODARONE HCL                     |
| 00185014490 | AMIODARONE HCL                     |
| 00245014001 | PACERONE                           |
| 00245014030 | PACERONE                           |
| 00245014401 | PACERONE                           |
| 00245014411 | PACERONE                           |
| 00245014430 | PACERONE                           |
| 00245014489 | PACERONE                           |
| 00245014501 | PACERONE                           |
| 00245014511 | PACERONE                           |
| 00245014515 | PACERONE                           |
| 00245014530 | PACERONE                           |
| 00245014589 | PACERONE                           |
| 00245014701 | PACERONE                           |
| 00245014715 | PACERONE                           |
| 00245014760 | PACERONE                           |
| 00245014789 | PACERONE                           |
| 00245014790 | PACERONE                           |
| 00409193302 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193303 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193401 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193411 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409434835 | AMIODARONE HYDROCHLORIDE           |
| 00409434849 | NOVAPLUS AMIODARONE HYDROCHLORIDE  |
| 00548138000 | AMIODARONE HCL INJECTION           |
| 00548138100 | AMIODARONE HCL INJECTION           |
| 00548338000 | AMIODARONE HCL                     |
| 00555091704 | AMIODARONE HCL                     |
| 00555091709 | AMIODARONE HCL                     |
| 00615454505 | AMIODARONE HCL TABLET              |
| 00615454531 | AMIODARONE HCL TABLET              |
| 00615454539 | AMIODARONE HCL TABLET              |
| 00703133201 | AMIODARONE HCL                     |
| 00703133203 | AMIODARONE HYDROCHLORIDE           |

| <b>NDC</b>  | <b>DESCRIPTION</b>                 |
|-------------|------------------------------------|
| 00703133501 | AMIODARONE HCL                     |
| 00703133601 | AMIODARONE HCL                     |
| 00781120305 | AMIODARONE HCL                     |
| 00781120360 | AMIODARONE HCL                     |
| 00781120392 | AMIODARONE HCL                     |
| 10019013101 | AMIODARONE HCL                     |
| 10019013301 | AMIODARONE HCL                     |
| 10019013302 | AMIODARONE HCL                     |
| 10019013304 | AMIODARONE HCL                     |
| 10019013313 | AMIODARONE HCL                     |
| 10019013319 | AMIODARONE HCL                     |
| 10019013389 | AMIODARONE HCL                     |
| 10139005003 | AMIODARONE HCL                     |
| 10139005009 | AMIODARONE HCL                     |
| 10139005010 | AMIODARONE HCL                     |
| 10139005011 | AMIODARONE HCL                     |
| 10139005028 | AMIODARONE HCL                     |
| 13107005605 | AMIODARONE HYDROCHLORIDE           |
| 13107005660 | AMIODARONE HYDROCHLORIDE           |
| 17236007560 | AMIODARONE HCL                     |
| 21695079630 | AMIODARONE HCL                     |
| 21695079660 | AMIODARONE HCL                     |
| 21695079690 | AMIODARONE HCL                     |
| 25021030266 | AMIODARONE HCL INJECTION, SOLUTION |
| 25021030273 | AMIODARONE HYDROCHLORIDE           |
| 35356000110 | AMIODARONE                         |
| 35356000190 | AMIODARONE HCL                     |
| 38245013325 | AMIODARONE HCL                     |
| 38245013355 | AMIODARONE HCL                     |
| 38245013368 | AMIODARONE HCL                     |
| 38779048605 | AMIODARONE HCL                     |
| 38779048608 | AMIODARONE HCL                     |
| 43066015010 | NEXTERONE                          |
| 43066015020 | NEXTERONE                          |
| 43066036020 | NEXERONE INJECTION, SOLUTION       |
| 47463001360 | AMIODARONE HCL                     |
| 49349015402 | AMIODARONE HCL TABLET              |
| 49884045802 | AMIODARONE HCL                     |
| 49884045804 | AMIODARONE HCL                     |
| 49884045805 | AMIODARONE HCL                     |
| 51079090601 | AMIODARONE HCL                     |
| 51079090617 | AMIODARONE HYDROCHLORIDE           |
| 51079090619 | AMIODARONE HYDROCHLORIDE           |
| 51079090620 | AMIODARONE HCL                     |
| 51138049130 | AMIODARONE HCL                     |
| 51672402503 | AMIODARONE HCL TABLET              |
| 51672402504 | AMIODARONE HCL                     |
| 51672405506 | AMIODARONE HCL TABLET              |

| <b>NDC</b>  | <b>DESCRIPTION</b>                              |
|-------------|-------------------------------------------------|
| 51672405600 | AMIODARONE HCL TABLET                           |
| 51672405601 | AMIODARONE HCL TABLET                           |
| 51672405603 | AMIODARONE HCL TABLET                           |
| 51672405606 | AMIODARONE HCL TABLET                           |
| 51672405700 | AMIODARONE HCL                                  |
| 51672405706 | AMIODARONE HCL                                  |
| 51862015560 | AMIODARONE HCL TABLET                           |
| 51862015630 | AMIODARONE HCL TABLET                           |
| 51927376000 | AMIODARONE HYDROCHLORIDE                        |
| 52125099202 | AMIODARONE HCL TABLET                           |
| 52533010158 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52533010159 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584015303 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584034835 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 52584087501 | AMIODARONE HCL INJECTION                        |
| 53808106601 | AMIODARONE HCL TABLET                           |
| 54569176500 | CORDARONE                                       |
| 54569514000 | AMIODARONE HCL                                  |
| 54569514001 | AMIODARONE HCL                                  |
| 54569612900 | AMIODARONE HCL                                  |
| 54868461800 | AMIODARONE HCL                                  |
| 54868461801 | AMIODARONE HCL                                  |
| 54868461802 | AMIODARONE HCL                                  |
| 54868461803 | AMIODARONE HCL                                  |
| 54868518600 | PACERONE                                        |
| 54868572200 | AMIODARONE                                      |
| 55045286400 | AMIODARONE                                      |
| 55045286406 | AMIODARONE                                      |
| 55048001360 | AMIODARONE HCL                                  |
| 55154499600 | PACERONE                                        |
| 55154549200 | PACERONE                                        |
| 55154560600 | PACERONE                                        |
| 55390005701 | AMIODARONE HCL                                  |
| 55390005710 | AMIODARONE HCL                                  |
| 55390005810 | AMIODARONE HCL                                  |
| 55390009710 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 55390010501 | AMIODARONE HCL                                  |
| 55648073901 | AMIODARONE HCL INJECTION                        |
| 55648073902 | AMIODARONE HCL INJECTION                        |
| 55648073904 | AMIODARONE HCL INJECTION                        |
| 55648078001 | AMIODARONE HCL INJECTION                        |
| 55887079801 | AMIODARONE                                      |
| 55887079830 | AMIODARONE                                      |
| 55953021440 | AMIODARONE HCL                                  |
| 55953021441 | AMIODARONE HCL                                  |
| 55953021470 | AMIODARONE HCL                                  |
| 57315000901 | AMIODARONE HCL TABLET                           |
| 57315000902 | AMIODARONE HCL TABLET                           |



| <b>NDC</b>  | <b>DESCRIPTION</b>                              |
|-------------|-------------------------------------------------|
| 57315000904 | AMIODARONE HCL TABLET                           |
| 58016030400 | AMIODARONE                                      |
| 58016030430 | AMIODARONE                                      |
| 58016030460 | AMIODARONE                                      |
| 58016030490 | AMIODARONE                                      |
| 60429024705 | AMIODARONE HCL                                  |
| 60429024760 | AMIODARONE HCL                                  |
| 60505072200 | AMIODARONE HCL                                  |
| 60505072201 | AMIODARONE HCL                                  |
| 60505265800 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265803 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265806 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265808 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 61703024103 | AMIODARONE HCL                                  |
| 61786030931 | AMIODARONE HCL TABLET                           |
| 62086015303 | AMIODARONE HCL                                  |
| 63323061603 | AMIODARONE HYDROCHLORIDE                        |
| 63323061609 | AMIODARONE HYDROCHLORIDE                        |
| 63323061613 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 63739038710 | AMIODARONE HYDROCHLORIDE                        |
| 64679073901 | AMIODARONE HCL INJECTION                        |
| 64679073902 | AMIODARONE HCL INJECTION                        |
| 64679078001 | AMIODARONE HCL INJECTION                        |
| 65084045618 | PACERONE                                        |
| 65084045620 | PACERONE                                        |
| 65841063105 | AMIODARONE HCL TABLET                           |
| 65841063106 | AMIODARONE HCL TABLET                           |
| 65841063110 | AMIODARONE HCL TABLET                           |
| 65841063114 | AMIODARONE HCL TABLET                           |
| 65841063130 | AMIODARONE HCL TABLET                           |
| 67457015300 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 67457015303 | AMIODARONE HCL                                  |
| 67457015309 | AMIODARONE HYDROCHLORIDE                        |
| 67457015318 | AMIODARONE HYDROCHLORIDE                        |
| 67544017630 | AMIODARONE HCL                                  |
| 67544057030 | PACERONE                                        |
| 68084037101 | AMIODARONE HYDROCHLORIDE                        |
| 68084037111 | AMIODARONE HCL                                  |
| 68382022705 | AMIODARONE HYDROCHLORIDE                        |
| 68382022706 | AMIODARONE HCL TABLET                           |
| 68382022710 | AMIODARONE HCL TABLET                           |
| 68382022714 | AMIODARONE HYDROCHLORIDE                        |
| 68382022730 | AMIODARONE HCL TABLET                           |
| 68382022777 | AMIODARONE HCL TABLET                           |
| 76237010830 | AMIODARONE HCL TABLET                           |

End

3) **Sotalol** – Betapace, Betapace AF, Sorine, Sorine AF

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00093106001 | SOTALOL HCL        |
| 00093106101 | SOTALOL HCL        |
| 00093106201 | SOTALOL HCL        |
| 00093106301 | SOTALOL HCL        |
| 00093740106 | SOTALOL HCL AF     |
| 00093740206 | SOTALOL HCL AF     |
| 00093740306 | SOTALOL HCL AF     |
| 00115271101 | SOTALOL HCL        |
| 00115271102 | SOTALOL HCL        |
| 00115271103 | SOTALOL HCL        |
| 00115272201 | SOTALOL HCL        |
| 00115272202 | SOTALOL HCL        |
| 00115272203 | SOTALOL HCL        |
| 00115273301 | SOTALOL HCL        |
| 00115273302 | SOTALOL HCL        |
| 00115273303 | SOTALOL HCL        |
| 00115274401 | SOTALOL HCL        |
| 00115274402 | SOTALOL HCL        |
| 00115274403 | SOTALOL HCL        |
| 00185017001 | SOTALOL HCL        |
| 00185017005 | SOTALOL HCL        |
| 00185017009 | SOTALOL HCL        |
| 00185017101 | SOTALOL HCL        |
| 00185017105 | SOTALOL HCL        |
| 00185017109 | SOTALOL HCL        |
| 00185017401 | SOTALOL HCL        |
| 00185017405 | SOTALOL HCL        |
| 00185017409 | SOTALOL HCL        |
| 00185017701 | SOTALOL HCL        |
| 00185017705 | SOTALOL HCL        |
| 00185017709 | SOTALOL HCL        |
| 00245001201 | SORINE             |
| 00245001211 | SORINE             |
| 00245001289 | SORINE             |
| 00245001301 | SORINE             |
| 00245001311 | SORINE             |
| 00245001389 | SORINE             |
| 00245001401 | SORINE             |
| 00245001411 | SORINE             |
| 00245001489 | SORINE             |
| 00245001501 | SORINE             |
| 00245001511 | SORINE             |
| 00245001589 | SORINE             |
| 00378030501 | SOTALOL HCL        |
| 00378031001 | SOTALOL HCL        |
| 00378031401 | SOTALOL HCL        |
| 00378512301 | SOTALOL HCL        |
| 00378512401 | SOTALOL HCL        |
| 00378512501 | SOTALOL HCL        |
| 00440836030 | SOTALOL HCL        |
| 00440836060 | SOTALOL HCL        |
| 00440836090 | SOTALOL HCL        |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00440836091 | SOTALOL HCL        |
| 00440836130 | SOTALOL HCL        |
| 00440836160 | SOTALOL HCL        |
| 00440836190 | SOTALOL HCL        |
| 00440836191 | SOTALOL HCL        |
| 00440836230 | SOTALOL HCL        |
| 00440836260 | SOTALOL HCL        |
| 00440836290 | SOTALOL HCL        |
| 00440836291 | SOTALOL HCL        |
| 00603576910 | SOTALOL HCL        |
| 00603576921 | SOTALOL HCL        |
| 00603576928 | SOTALOL HCL        |
| 00603576929 | SOTALOL HCL        |
| 00603576932 | SOTALOL HCL        |
| 00603577010 | SOTALOL HCL        |
| 00603577021 | SOTALOL HCL        |
| 00603577025 | SOTALOL HCL        |
| 00603577028 | SOTALOL HCL        |
| 00603577029 | SOTALOL HCL        |
| 00603577032 | SOTALOL HCL        |
| 00603577110 | SOTALOL HCL        |
| 00603577121 | SOTALOL HCL        |
| 00603577128 | SOTALOL HCL        |
| 00603577129 | SOTALOL HCL        |
| 00603577132 | SOTALOL HCL        |
| 00603577221 | SOTALOL HCL        |
| 00603577228 | SOTALOL HCL        |
| 00603577229 | SOTALOL HCL        |
| 00677170901 | SOTALOL HCL        |
| 00677170905 | SOTALOL HCL        |
| 00677170906 | SOTALOL HCL        |
| 00677170907 | SOTALOL HCL        |
| 00677171001 | SOTALOL HCL        |
| 00677171005 | SOTALOL HCL        |
| 00677171006 | SOTALOL HCL        |
| 00677171101 | SOTALOL HCL        |
| 00677171105 | SOTALOL HCL        |
| 00677171106 | SOTALOL HCL        |
| 00677171201 | SOTALOL HCL        |
| 00677171205 | SOTALOL HCL        |
| 00677171206 | SOTALOL HCL        |
| 00677171207 | SOTALOL HCL        |
| 00677189301 | SOTALOL HCL AF     |
| 00677189306 | SOTALOL HCL AF     |
| 00677189401 | SOTALOL HCL AF     |
| 00677189406 | SOTALOL HCL AF     |
| 00677189501 | SOTALOL HCL AF     |
| 00677189506 | SOTALOL HCL AF     |
| 15330020801 | SOTALOL HCL        |
| 15330020901 | SOTALOL HCL        |
| 15330021001 | SOTALOL HCL        |
| 21695039730 | SOTALOL            |
| 24338053025 | SOTYLIZE SOLUTION  |
| 24338053048 | SOTYLIZE SOLUTION  |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 35356093530 | SOTALOL HCL        |
| 35356093560 | SOTALOL HCL        |
| 35356093590 | SOTALOL HCL        |
| 35356096430 | SOTALOL HCL        |
| 35356096460 | SOTALOL HCL        |
| 35356096490 | SOTALOL HCL        |
| 42291076001 | SOTALOL HCL        |
| 42291076101 | SOTALOL HCL        |
| 42291076201 | SOTALOL HCL        |
| 43063013330 | SOTALOL HCL        |
| 47463077830 | SOTALOL HCL AF     |
| 47463077930 | SOTALOL HCL AF     |
| 49884058201 | SOTALOL HCL        |
| 49884058210 | SOTALOL HCL        |
| 49884058301 | SOTALOL HCL        |
| 49884058310 | SOTALOL HCL        |
| 49884058401 | SOTALOL HCL        |
| 49884058410 | SOTALOL HCL        |
| 49884058501 | SOTALOL HCL        |
| 49884058510 | SOTALOL HCL        |
| 50419010510 | BETAPACE           |
| 50419010511 | BETAPACE           |
| 50419010610 | BETAPACE           |
| 50419010611 | BETAPACE           |
| 50419010710 | BETAPACE           |
| 50419010711 | BETAPACE           |
| 50419010910 | BETAPACE           |
| 50419010911 | BETAPACE           |
| 50419011506 | BETAPACE AF        |
| 50419011511 | BETAPACE AF        |
| 50419011606 | BETAPACE AF        |
| 50419011611 | BETAPACE AF        |
| 50419011906 | BETAPACE AF        |
| 50419011911 | BETAPACE AF        |
| 51138056130 | SOTALOL HCL        |
| 51138056230 | SOTALOL HCL        |
| 51138056330 | SOTALOL HCL        |
| 51138056430 | SOTALOL HCL        |
| 52544065401 | SOTALOL HCL        |
| 52544065501 | SOTALOL HCL        |
| 52544065601 | SOTALOL HCL        |
| 52544066501 | SOTALOL HCL        |
| 53217001190 | SOTALOL HCL        |
| 53489028801 | SOTALOL HCL        |
| 53489028802 | SOTALOL HCL        |
| 53489028803 | SOTALOL HCL        |
| 53489028805 | SOTALOL HCL        |
| 53489028810 | SOTALOL HCL        |
| 53489028901 | SOTALOL HCL        |
| 53489028902 | SOTALOL HCL        |
| 53489028903 | SOTALOL HCL        |
| 53489028905 | SOTALOL HCL        |
| 53489028910 | SOTALOL HCL        |
| 53489029001 | SOTALOL HCL        |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 53489029002 | SOTALOL HCL        |
| 53489029003 | SOTALOL HCL        |
| 53489029005 | SOTALOL HCL        |
| 53489029010 | SOTALOL HCL        |
| 53489029101 | SOTALOL HCL        |
| 53489029102 | SOTALOL HCL        |
| 53489029103 | SOTALOL HCL        |
| 53489029105 | SOTALOL HCL        |
| 53489029110 | SOTALOL HCL        |
| 53489050301 | SOTALOL            |
| 53489050303 | SOTALOL            |
| 53489050305 | SOTALOL            |
| 53489050306 | SOTALOL            |
| 53489050307 | SOTALOL            |
| 53489050310 | SOTALOL            |
| 53489050401 | SOTALOL            |
| 53489050403 | SOTALOL            |
| 53489050405 | SOTALOL            |
| 53489050406 | SOTALOL            |
| 53489050407 | SOTALOL            |
| 53489050410 | SOTALOL            |
| 53489050501 | SOTALOL            |
| 53489050503 | SOTALOL            |
| 53489050505 | SOTALOL            |
| 53489050506 | SOTALOL            |
| 53489050507 | SOTALOL            |
| 53489050510 | SOTALOL            |
| 54569443400 | BETAPACE           |
| 54569443500 | BETAPACE           |
| 54868442300 | BETAPACE AF        |
| 54868442301 | BETAPACE AF        |
| 54868443500 | SOTALOL HCL        |
| 54868443501 | SOTALOL HCL        |
| 54868443502 | SOTALOL HCL        |
| 54868443503 | SOTALOL HCL        |
| 54868554900 | SOTALOL HCL        |
| 54868554901 | SOTALOL HCL        |
| 54868561400 | SOTALOL HCL        |
| 54868561401 | SOTALOL HCL AF     |
| 55045316000 | SOTALOL HCL        |
| 55048077830 | SOTALOL HCL AF     |
| 55048077930 | SOTALOL HCL AF     |
| 57866903201 | SOTALOL HCL        |
| 57866903202 | SOTALOL HCL        |
| 57866903203 | SOTALOL HCL        |
| 57866903204 | SOTALOL HCL        |
| 57866903301 | SOTALOL HCL        |
| 57866903302 | SOTALOL HCL        |
| 57866903303 | SOTALOL HCL        |
| 57866903304 | SOTALOL HCL        |
| 57866903401 | SOTALOL HCL        |
| 57866903402 | SOTALOL HCL        |
| 57866903403 | SOTALOL HCL        |
| 57866903404 | SOTALOL HCL        |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 58016018800 | SOTALOL HCL        |
| 58016018802 | SOTALOL HCL        |
| 58016018830 | SOTALOL HCL        |
| 58016018860 | SOTALOL HCL        |
| 58016018890 | SOTALOL HCL        |
| 60429039001 | SOTALOL HCL        |
| 60429039060 | SOTALOL HCL        |
| 60429039101 | SOTALOL HCL        |
| 60429039160 | SOTALOL HCL        |
| 60429039201 | SOTALOL HCL        |
| 60429039260 | SOTALOL HCL        |
| 60429074801 | SOTALOL HCL        |
| 60429074901 | SOTALOL HCL        |
| 60429075001 | SOTALOL HCL        |
| 60429075101 | SOTALOL HCL        |
| 60429094801 | SOTALOL HCL        |
| 60429094901 | SOTALOL HCL        |
| 60429095001 | SOTALOL HCL        |
| 60429095101 | SOTALOL HCL        |
| 60505008000 | SOTALOL HCL        |
| 60505008010 | SOTALOL HCL        |
| 60505008100 | SOTALOL HCL        |
| 60505008110 | SOTALOL HCL        |
| 60505008200 | SOTALOL HCL        |
| 60505008201 | SOTALOL HCL        |
| 60505015900 | SOTALOL HCL        |
| 60505022201 | SOTALOL HCL AF     |
| 60505022210 | SOTALOL HCL        |
| 60505022220 | SOTALOL HCL        |
| 60505022301 | SOTALOL HCL AF     |
| 60505022310 | SOTALOL HCL        |
| 60505022320 | SOTALOL HCL        |
| 60505022401 | SOTALOL HCL AF     |
| 60505022410 | SOTALOL HCL        |
| 60505022420 | SOTALOL HCL        |
| 62451010510 | SOTALOL HCL        |
| 62451010610 | SOTALOL HCL        |
| 62451010710 | SOTALOL HCL        |
| 62451010910 | SOTALOL HCL        |
| 63629471910 | SOTALOL HCL        |
| 63629472010 | SOTALOL HCL        |
| 63629472020 | SOTALOL HCL        |
| 65162072510 | SOTALOL HCL        |
| 65162072710 | SOTALOL HCL        |
| 65162073110 | SOTALOL HCL        |
| 67457017610 | SOTALOL HCL        |
| 68084038701 | SOTALOL HCL        |
| 68084038711 | SOTALOL HCL        |
| 68084049701 | SOTALOL HCL        |
| 68084049711 | SOTALOL HCL        |
| 68084065401 | SOTALOL HCL        |
| 68084065411 | SOTALOL HCL        |
| 68115066100 | SOTALOL HCL        |
| 68151270290 | SOTALOL HCL        |

4) **Flecainide** – Tambocor

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00054001020 | FLECAINIDE ACETATE |
| 00054001021 | FLECAINIDE ACETATE |
| 00054001025 | FLECAINIDE ACETATE |
| 00054001120 | FLECAINIDE ACETATE |
| 00054001121 | FLECAINIDE ACETATE |
| 00054001125 | FLECAINIDE ACETATE |
| 00054001220 | FLECAINIDE ACETATE |
| 00054001221 | FLECAINIDE ACETATE |
| 00054001225 | FLECAINIDE ACETATE |
| 00089030510 | TAMBOCOR           |
| 00089030516 | TAMBOCOR           |
| 00089030710 | TAMBOCOR           |
| 00089030716 | TAMBOCOR           |
| 00089031410 | TAMBOCOR           |
| 00089031416 | TAMBOCOR           |
| 00378850501 | FLECAINIDE ACETATE |
| 00378851001 | FLECAINIDE ACETATE |
| 00378851501 | FLECAINIDE ACETATE |
| 00440754260 | FLECAINIDE ACETATE |
| 00440754360 | FLECAINIDE ACETATE |
| 00440754460 | FLECAINIDE ACETATE |
| 00555085902 | FLECAINIDE ACETATE |
| 00555086002 | FLECAINIDE ACETATE |
| 00555086102 | FLECAINIDE ACETATE |
| 00781506201 | FLECAINIDE ACETATE |
| 00781506301 | FLECAINIDE ACETATE |
| 00781506401 | FLECAINIDE ACETATE |
| 12280018230 | TAMBOCOR           |
| 29336030510 | TAMBOCOR           |
| 29336030710 | TAMBOCOR           |
| 29336031410 | TAMBOCOR           |
| 29366031410 | TAMBOCOR           |
| 49884069401 | FLECAINIDE ACETATE |
| 49884069501 | FLECAINIDE ACETATE |
| 49884069601 | FLECAINIDE ACETATE |
| 50268032011 | FLECAINIDE ACETATE |
| 50268032015 | FLECAINIDE ACETATE |
| 50268032111 | FLECAINIDE ACETATE |
| 50268032115 | FLECAINIDE ACETATE |
| 50268032211 | FLECAINIDE ACETATE |
| 50268032215 | FLECAINIDE ACETATE |
| 51079098701 | FLECAINIDE ACETATE |
| 51079098720 | FLECAINIDE ACETATE |
| 51079098820 | FLECAINIDE ACETATE |
| 54569050000 | TAMBOCOR           |
| 54569613100 | FLECAINIDE ACETATE |
| 54569613200 | FLECAINIDE ACETATE |
| 54868440700 | TAMBOCOR           |
| 54868506500 | TAMBOCOR           |
| 54868506501 | TAMBOCOR           |
| 54868507400 | FLECAINIDE ACETATE |
| 54868507401 | FLECAINIDE ACETATE |

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 54868507402 | FLECAINIDE ACETATE |
| 54868507403 | FLECAINIDE ACETATE |
| 54868540500 | FLECAINIDE ACETATE |
| 54868540501 | FLECAINIDE ACETATE |
| 54868558600 | FLECAINIDE         |
| 54868558601 | FLECAINIDE ACETATE |
| 55045381901 | FLECAINIDE ACETATE |
| 58016096202 | FLECAINIDE ACETATE |
| 58016096203 | FLECAINIDE ACETATE |
| 58016096204 | FLECAINIDE ACETATE |
| 58016096230 | FLECAINIDE ACETATE |
| 58016096240 | FLECAINIDE ACETATE |
| 58016096256 | FLECAINIDE ACETATE |
| 58016096260 | FLECAINIDE ACETATE |
| 58016096290 | FLECAINIDE ACETATE |
| 60505266000 | FLECAINIDE ACETATE |
| 60505266001 | FLECAINIDE ACETATE |
| 60505266003 | FLECAINIDE ACETATE |
| 60505266005 | FLECAINIDE ACETATE |
| 60505266008 | FLECAINIDE ACETATE |
| 60505266100 | FLECAINIDE ACETATE |
| 60505266101 | FLECAINIDE ACETATE |
| 60505266103 | FLECAINIDE ACETATE |
| 60505266105 | FLECAINIDE ACETATE |
| 60505266108 | FLECAINIDE ACETATE |
| 60505266200 | FLECAINIDE ACETATE |
| 60505266201 | FLECAINIDE ACETATE |
| 60505266203 | FLECAINIDE ACETATE |
| 60505266205 | FLECAINIDE ACETATE |
| 63304079401 | FLECAINIDE ACETATE |
| 63304079501 | FLECAINIDE ACETATE |
| 63304079601 | FLECAINIDE ACETATE |
| 65162064110 | FLECAINIDE ACETATE |
| 65162064111 | FLECAINIDE ACETATE |
| 65162064210 | FLECAINIDE ACETATE |
| 65162064211 | FLECAINIDE ACETATE |
| 65162064310 | FLECAINIDE ACETATE |
| 65162064311 | FLECAINIDE ACETATE |
| 66105015202 | TAMBOCOR           |
| 66105015203 | TAMBOCOR           |
| 66105015206 | TAMBOCOR           |
| 66105015209 | TAMBOCOR           |
| 66105015210 | TAMBOCOR           |
| 68084054011 | FLECAINIDE ACETATE |
| 68084054021 | FLECAINIDE ACETATE |
| 68151146402 | FLECAINIDE ACETATE |
| 99207018050 | TAMBOCOR           |
| 99207018110 | TAMBOCOR           |
| 99207018215 | TAMBOCOR           |

End



5) **Dofetilide** – Tikosyn

| <b>NDC</b>  | <b>DESCRIPTION</b> |
|-------------|--------------------|
| 00069580043 | TIKOSYN            |
| 00069580060 | TIKOSYN            |
| 00069580061 | TIKOSYN            |
| 00069581043 | TIKOSYN            |
| 00069581060 | TIKOSYN            |
| 00069581061 | TIKOSYN            |
| 00069582043 | TIKOSYN            |
| 00069582060 | TIKOSYN            |
| 00069582061 | TIKOSYN            |

End

**Propafenone – Rythmol, Rythmol SR**

| <b>NDC</b>  | <b>DESCRIPTION</b>            |
|-------------|-------------------------------|
| 00044502202 | RYTHMOL                       |
| 00044502210 | RYTHMOL                       |
| 00044502302 | RYTHMOL                       |
| 00044502310 | RYTHMOL                       |
| 00044502402 | RYTHMOL                       |
| 00044502410 | RYTHMOL                       |
| 00074162812 | RYTHMOL                       |
| 00074162814 | RYTHMOL                       |
| 00074173212 | RYTHMOL                       |
| 00074173214 | RYTHMOL                       |
| 00074183112 | RYTHMOL                       |
| 00074183114 | RYTHMOL                       |
| 00173078601 | RYTHMOL SR                    |
| 00173078801 | RYTHMOL SR                    |
| 00173078901 | RYTHMOL SR                    |
| 00173079220 | RYTHMOL                       |
| 00173079420 | RYTHMOL                       |
| 00173082318 | RYTHMOL SR                    |
| 00173082418 | RYTHMOL SR                    |
| 00173082618 | RYTHMOL SR                    |
| 00591058201 | PROPAFENONE HCL               |
| 00591058301 | PROPAFENONE HCL               |
| 00603544810 | PROPAFENONE, FILM COATED      |
| 00603544821 | PROPAFENONE HCL               |
| 00603544825 | PROPAFENONE HCL               |
| 00603544828 | PROPAFENONE, FILM COATED      |
| 00603544832 | PROPAFENONE, FILM COATED      |
| 00603544910 | PROPAFENONE, FILM COATED      |
| 00603544921 | PROPAFENONE HCL               |
| 00603544925 | PROPAFENONE, FILM COATED      |
| 00603544928 | PROPAFENONE, FILM COATED      |
| 00603544932 | PROPAFENONE, FILM COATED      |
| 00603545010 | PROPAFENONE, FILM COATED      |
| 00603545021 | PROPAFENONE HCL               |
| 00603545028 | PROPAFENONE, FILM COATED      |
| 00603545032 | PROPAFENONE, FILM COATED      |
| 00615757439 | PROPAFENONE, FILM COATED      |
| 00677181501 | PROPAFENONE HCL               |
| 00677181503 | PROPAFENONE HCL               |
| 00677181505 | PROPAFENONE HCL               |
| 00677181601 | PROPAFENONE HCL               |
| 00677181603 | PROPAFENONE HCL               |
| 00677181605 | PROPAFENONE HCL               |
| 00677181701 | PROPAFENONE HCL               |
| 00677181703 | PROPAFENONE HCL               |
| 00677181705 | PROPAFENONE HCL               |
| 05515509500 | PROPAFENONE, FILM COATED      |
| 21695081460 | PROPAFENONE HCL ER            |
| 49884009901 | PROPAFENONE, EXTENDED RELEASE |
| 49884009902 | PROPAFENONE HCL ER            |
| 49884009905 | PROPAFENONE HCL ER            |
| 49884009909 | PROPAFENONE HCL ER            |

| <b>NDC</b>  | <b>DESCRIPTION</b>            |
|-------------|-------------------------------|
| 49884009910 | PROPAFENONE, EXTENDED RELEASE |
| 49884011301 | PROPAFENONE, EXTENDED RELEASE |
| 49884011302 | PROPAFENONE, EXTENDED RELEASE |
| 49884011305 | PROPAFENONE, EXTENDED RELEASE |
| 49884011309 | PROPAFENONE, EXTENDED RELEASE |
| 49884011310 | PROPAFENONE, EXTENDED RELEASE |
| 49884020902 | PROPAFENONE HCL ER            |
| 49884020905 | PROPAFENONE HCL ER            |
| 49884020909 | PROPAFENONE HCL ER            |
| 49884021001 | PROPAFENONE, EXTENDED RELEASE |
| 49884021002 | PROPAFENONE HCL ER            |
| 49884021005 | PROPAFENONE HCL ER            |
| 49884021009 | PROPAFENONE HCL ER            |
| 49884021010 | PROPAFENONE, EXTENDED RELEASE |
| 49884021101 | PROPAFENONE, EXTENDED RELEASE |
| 49884021102 | PROPAFENONE HCL ER            |
| 49884021105 | PROPAFENONE HCL ER            |
| 49884021109 | PROPAFENONE HCL ER            |
| 49884021110 | PROPAFENONE, EXTENDED RELEASE |
| 50111070801 | PROPAFENONE HCL               |
| 50111070901 | PROPAFENONE HCL               |
| 50111071001 | PROPAFENONE HCL               |
| 51079099601 | PROPAFENONE HCL               |
| 51079099620 | PROPAFENONE HCL               |
| 52544058201 | PROPAFENONE HCL               |
| 52544058301 | PROPAFENONE HCL               |
| 53489055101 | PROPAFENONE HCL               |
| 53489055103 | PROPAFENONE HCL               |
| 53489055105 | PROPAFENONE HCL               |
| 53489055107 | PROPAFENONE, FILM COATED      |
| 53489055110 | PROPAFENONE, FILM COATED      |
| 53489055201 | PROPAFENONE HCL               |
| 53489055203 | PROPAFENONE HCL               |
| 53489055205 | PROPAFENONE HCL               |
| 53489055207 | PROPAFENONE, FILM COATED      |
| 53489055210 | PROPAFENONE, FILM COATED      |
| 53489055301 | PROPAFENONE HCL               |
| 53489055303 | PROPAFENONE HCL               |
| 53489055305 | PROPAFENONE HCL               |
| 53489055307 | PROPAFENONE, FILM COATED      |
| 53489055310 | PROPAFENONE, FILM COATED      |
| 54569613300 | PROPAFENONE HCL               |
| 54868477000 | PROPAFENONE HCL               |
| 54868477001 | PROPAFENONE HYDROCHLORIDE     |
| 54868477002 | PROPAFENONE HYDROCHLORIDE     |
| 54868477003 | PROPAFENONE HCL               |
| 54868477004 | PROPAFENONE HYDROCHLORIDE     |
| 54868477005 | PROPAFENONE HYDROCHLORIDE     |
| 54868595000 | PROPAFENONE HCL               |
| 54868595001 | PROPAFENONE HCL               |
| 54868595002 | PROPAFENONE, FILM COATED      |
| 58016030300 | PROPAFENONE                   |
| 58016030330 | PROPAFENONE                   |
| 58016030360 | PROPAFENONE                   |

| <b>NDC</b>  | <b>DESCRIPTION</b>        |
|-------------|---------------------------|
| 58016030390 | PROPAFENONE               |
| 58177033104 | PROPAFENONE HCL           |
| 58177033111 | PROPAFENONE HCL           |
| 58177033112 | PROPAFENONE HCL           |
| 58177033204 | PROPAFENONE HCL           |
| 58177033304 | PROPAFENONE HCL           |
| 62559023001 | PROPAFENONE, FILM COATED  |
| 62559023101 | PROPAFENONE, FILM COATED  |
| 62559023201 | PROPAFENONE, FILM COATED  |
| 63629386901 | PROPAFENONE HCL           |
| 63739050910 | PROPAFENONE, FILM COATED  |
| 63739051010 | PROPAFENONE, FILM COATED  |
| 65726026115 | RYTHMOL SR                |
| 65726026125 | RYTHMOL SR                |
| 65726026190 | RYTHMOL SR                |
| 65726026215 | RYTHMOL SR                |
| 65726026225 | RYTHMOL SR                |
| 65726026290 | RYTHMOL SR                |
| 65726026315 | RYTHMOL SR                |
| 65726026325 | RYTHMOL SR                |
| 65726026390 | RYTHMOL SR                |
| 65726026525 | RYTHMOL                   |
| 65726026590 | RYTHMOL                   |
| 65726026625 | RYTHMOL                   |
| 65726026690 | RYTHMOL                   |
| 65726026725 | RYTHMOL                   |
| 65726026790 | RYTHMOL                   |
| 66993011460 | PROPAFENONE SR            |
| 66993011560 | PROPAFENONE SR            |
| 66993011660 | PROPAFENONE SR            |
| 68084036101 | PROPAFENONE HYDROCHLORIDE |
| 68084036111 | PROPAFENONE HCL           |
| 68084085832 | PROPAFENONE ER            |
| 68084085833 | PROPAFENONE ER            |
| 68084091732 | PROPAFENONE ER            |
| 68084091733 | PROPAFENONE ER            |

End

## APPENDIX 4. EXCLUSIONARY CONDITIONS DEFINITIONS

### History of Cancer

#### ICD-9-CM Diagnosis Range

140 – 209.xx Cancer

V10.x Personal history of malignant neoplasms

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### History of Organ Transplant

#### ICD-9-CM Diagnoses

996.81 Complications of a transplanted kidney  
996.82 Complications of a transplanted liver  
996.83 Complications of a transplanted heart  
996.84 Complications of a transplanted lung  
996.86 Complications of a transplanted pancreas  
V42.0x Transplant – Kidney, status post  
V42.1x Transplant – Heart  
V42.6x Transplant – Lung  
V42.7x Transplant – Liver  
V42.83 Pancreas replaced by transplant

#### ICD-9-CM Procedures

33.5 Lung transplant  
33.50 Lung transplantation, not otherwise specified  
33.51 Unilateral lung transplantation  
33.52 Bilateral lung transplantation  
33.6 Combined heart-lung transplantation  
37.51 Heart transplantation  
37.55 Removal of internal biventricular heart replacement system  
50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver  
50.91 Percutaneous aspiration of liver  
52.8 Transplant of pancreas  
52.80 Pancreatic transplant, not otherwise specified  
52.81 Reimplantation of pancreatic tissue  
52.82 Homotransplant of pancreas  
52.83 Heterotransplant of pancreas  
52.84 Autotransplantation of cells of islets of langerhans  
52.85 Allotransplantation of cells of islets of langerhans  
52.86 Transplantation of cells of islets of langerhans, not otherwise specified  
55.53 Removal transplant/rejected kidney  
55.69 Other kidney transplantation

#### CPT® Procedures

32851 Lung transplant, single; without cardiopulmonary bypass  
32852 Lung transplant, single; with cardiopulmonary bypass

|       |                                                                                                          |
|-------|----------------------------------------------------------------------------------------------------------|
| 32853 | Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass                |
| 32854 | Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass                   |
| 33935 | Heart-lung transplant with recipient cardiectomy-pneumonectomy                                           |
| 33945 | Heart transplant, with or without recipient cardiectomy                                                  |
| 47135 | Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age           |
| 47136 | Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age          |
| 48160 | Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells |
| 48554 | Transplantation of pancreatic allograft                                                                  |
| 48556 | Removal of transplanted pancreatic allograft                                                             |
| 50360 | Renal allotransplantation, implantation of graft; without recipient nephrectomy                          |
| 50365 | Renal allotransplantation, implantation of graft; with recipient nephrectomy                             |
| 50370 | Removal of transplanted renal allograft                                                                  |
| 50380 | Renal autotransplantation, reimplantation of kidney                                                      |

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## History of HIV

### ICD-9-CM Diagnosis

|     |                                            |
|-----|--------------------------------------------|
| 042 | Human immunodeficiency virus (HIV) disease |
|-----|--------------------------------------------|

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## History of Pregnancy (Index date minus 280 days, through index date minus 1)

### ICD-9-CM Diagnoses

|        |                                                                                                 |
|--------|-------------------------------------------------------------------------------------------------|
| V22    | Normal pregnancy                                                                                |
| V22.0  | Supervision of normal first pregnancy                                                           |
| V22.1  | Supervision of other normal pregnancy                                                           |
| V22.2  | Pregnant state incidental                                                                       |
| V23    | Supervision of high-risk pregnancy                                                              |
| V23.0  | Supervision of high-risk pregnancy with history of infertility                                  |
| V23.1  | Supervision of high-risk pregnancy with history of trophoblastic disease                        |
| V23.2  | Supervision of high-risk pregnancy with history of abortion                                     |
| V23.3  | Supervision of high-risk pregnancy with grand multiparity                                       |
| V23.4  | Supervision of high-risk pregnancy with other poor obstetric history                            |
| V23.41 | Supervision of high-risk pregnancy with history of pre-term labor                               |
| V23.42 | Supervision of high-risk pregnancy with history of ectopic pregnancy                            |
| V23.49 | Supervision of high-risk pregnancy with other poor obstetric history                            |
| V23.5  | Supervision of high-risk pregnancy with other poor reproductive history                         |
| V23.7  | Supervision of high-risk pregnancy with insufficient prenatal care                              |
| V23.8  | Supervision of other high-risk pregnancy                                                        |
| V23.81 | Supervision of high-risk pregnancy with elderly primigravida                                    |
| V23.82 | Supervision of high-risk pregnancy with elderly multigravida                                    |
| V23.83 | Supervision of high-risk pregnancy with young primigravida                                      |
| V23.84 | Supervision of high-risk pregnancy with young multigravida                                      |
| V23.85 | Supervision of high-risk pregnancy resulting from assisted reproductive technology              |
| V23.86 | Supervision of high-risk pregnancy with history of in utero procedure during previous pregnancy |
| V23.87 | Supervision of high-risk pregnancy with inconclusive fetal viability                            |

- V23.89 Supervision of other high-risk pregnancy
- V23.9 Supervision of unspecified high-risk pregnancy
- V28 Encounter for antenatal screening of mother
- V28.0 Screening for chromosomal anomalies by amniocentesis
- V28.1 Screening for raised alpha-fetoprotein levels in amniotic fluid
- V28.2 Other antenatal screening based on amniocentesis
- V28.3 Encounter for routine screening for malformation using ultrasonics
- V28.4 Antenatal screening for fetal growth retardation using ultrasonics
- V28.5 Antenatal screening for isoimmunization
- V28.6 Antenatal screening for streptococcus b
- V28.8 Other specified antenatal screening
- V28.81 Encounter for fetal anatomic survey
- V28.82 Encounter for screening for risk of preterm labor
- V28.89 Other specified antenatal screening
- V28.9 Unspecified antenatal screening

### **ICD-9-CM Procedures**

- 72 Forceps, vacuum, and breech delivery
- 72.0 Low forceps operation
- 72.1 Low forceps operation with episiotomy
- 72.2 Mid forceps operation
- 72.21 Mid forceps operation with episiotomy
- 72.29 Other mid forceps operation
- 72.3 High forceps operation
- 72.31 High forceps operation with episiotomy
- 72.39 Other high forceps operation
- 72.4 Forceps rotation of fetal head
- 72.5 Breech extraction
- 72.51 Partial breech extraction with forceps to aftercoming head
- 72.52 Other partial breech extraction
- 72.53 Total breech extraction with forceps to aftercoming head
- 72.54 Other total breech extraction
- 72.6 Forceps application to aftercoming head
- 72.7 Vacuum extraction
- 72.71 Vacuum extraction with episiotomy
- 72.79 Other vacuum extraction
- 72.8 Other specified instrumental delivery
- 72.9 Unspecified instrumental delivery
- 73 Other procedures inducing or assisting delivery
- 73.0 Artificial rupture of membranes
- 73.01 Induction of labor by artificial rupture of membranes
- 73.09 Other artificial rupture of membranes
- 73.1 Other surgical induction of labor
- 73.2 Internal and combined version and extraction
- 73.21 Internal and combined version without extraction
- 73.22 Internal and combined version with extraction
- 73.3 Failed forceps
- 73.4 Medical induction of labor
- 73.5 Manually assisted delivery
- 73.51 Manual rotation of fetal head
- 73.59 Other manually assisted delivery
- 73.6 Episiotomy
- 73.8 Operations on fetus to facilitate delivery
- 73.9 Other operations assisting delivery
- 73.91 External version assisting delivery

- 73.92 Replacement of prolapsed umbilical cord
- 73.93 Incision of cervix to assist delivery
- 73.94 Pubiotomy to assist delivery
- 73.99 Other operations assisting delivery
- 74 Cesarean section and removal of fetus
- 74.0 Classical cesarean section
- 74.1 Low cervical cesarean section
- 74.2 Extraperitoneal cesarean section
- 74.3 Removal of extratubal ectopic pregnancy
- 74.4 Cesarean section of other specified type
- 74.9 Cesarean section of unspecified type
- 74.91 Hysterotomy to terminate pregnancy
- 74.99 Other cesarean section of unspecified type
- 75 Other obstetric operations
- 75.0 Intra-amniotic injection for abortion
- 75.1 Diagnostic amniocentesis
- 75.2 Intrauterine transfusion
- 75.3 Other intrauterine operations on fetus and amnion
- 75.31 Amnioscopy
- 75.32 Fetal ekg (scalp)
- 75.33 Fetal blood sampling and biopsy
- 75.34 Other fetal monitoring
- 75.35 Other diagnostic procedures on fetus and amnion
- 75.36 Correction of fetal defect
- 75.37 Amnioinfusion
- 75.38 Fetal pulse oximetry

#### **CPT® Procedures**

- 59120 Tx ectopic pregnancy abdominal/vaginal appr
- 59121 Tx ectopic pregnancy w/o salping&/oophorectomy
- 59130 Tx ectopic pregnancy abdl pregnancy
- 59135 Tx ectopic pregnancy ntrstl req tot hyst
- 59136 Tx ectopic pregnancy ntrstl prtl rescj uter
- 59140 Tx ectopic pregnancy cervical w/evacuation
- 59150 Laps tx ectopic preg w/o salping&/oophorectomy
- 59151 Laps tx ectopic preg w/salping&/oophorectomy
- 59160 Curettage postpartum
- 59200 Insertion cervical dilator separate procedure
- 59300 Episiotomy/vag rpr oth/thn attending
- 59320 Cerclage cervix pregnancy vaginal
- 59325 Cerclage cervix pregnancy abdominal
- 59350 Hysterorrhaphy ruptured uterus
- 59400 Ob care antepartum vag dlvr & postpartum
- 59409 Vaginal delivery only
- 59410 Vaginal delivery only w/postpartum care
- 59412 External cephalic version w/wo tocolysis
- 59414 Delivery placenta separate procedure
- 59425 Antepartum care only 4-6 visits
- 59426 Antepartum care only 7/> visits
- 59430 Postpartum care only separate procedure
- 59510 Ob antepartum care cesarean dlvr & postpartum
- 59514 Cesarean delivery only
- 59515 Cesarean delivery only w/postpartum care
- 59525 Stot/tot hysterectomy after cesaren delivery
- 59610 Routine ob care vag dlvr & postpartum care vb



59612 Vaginal delivery after cesarean delivery  
 59614 Vaginal delivery & postpartum care vbac  
 59618 Routine obstetrical care attempted vbac  
 59620 Cesarean delivery attempted vbac  
 59622 Cesarean dlrvy & postpartum care attempted vba  
 59812 Tx incomplete abortion any trimester surgical  
 59820 Tx missed abortion first trimester surgical  
 59821 Tx missed abortion second trimester surgical  
 59830 Tx septic abortion surgical  
 59840 Induced abortion dilation and curettage  
 59841 Induced abortion dilation & evaocation  
 59850 Induced abortion 1/> amniotic injx w/d&c/evacj  
 59851 Induce abort 1/> amniot njxs dlvr fetus d&c  
 59852 Induce abort 1/> amniot njxs dlvr fetus hystotm  
 59855 Induced abort 1/> vag suppositories dlvr fetus  
 59856 Induced abort 1/> vag supp dlvr fetus d&c &/evac  
 59857 Induced abort 1/> vag suppos dlvr fetus hystot  
 59866 Multifetal pregnancy reduction  
 59870 Uterine evacuation & curettage hydatidiform mole  
 59871 Removal cerclage suture under anesthesia  
 59897 Unlisted fetal invasive px w/ultrasound  
 59898 Unlisted laparoscopy px maternity care&delivery  
 59899 Unlisted procedure maternity care & delivery  
 76801 Us pregnant uterus 14 wk transabdl 1/1st gestat  
 76802 Us preg uterus 14 wk transabdl each gestation  
 76805 Us preg uterus after 1st trimest 1/1st gestation  
 76810 Us preg uterus > 1st trimester abdl ea gestatio  
 76811 Us preg uterus w/detail fetal anat 1st gestation  
 76812 Us preg uterus detail fetal anat exam ea gestat  
 76813 Us fetal nuchal translucency 1st gestation  
 76814 Us fetal nuchal translucency ea addl gestation  
 76815 Us pregnant uterus limited 1/> fetuses  
 76816 Us preg uterus real time f/u trnsabdl per fetus  
 76817 Us preg uterus real time w/image dcmtn transvag

---

## History of Pregnancy (Index Date plus 280 days)

### ICD-9-CM Diagnoses

631 – 639.xx Ectopic and molar pregnancy and other pregnancy with abortive outcomes  
 640 – 649.xx Complications mainly related to pregnancy  
 650 – 659.xx Normal delivery, and other indications for care in pregnancy, labor, and delivery  
 660 – 669.xx Complications occurring mainly in the course of labor and delivery  
 670 – 677.xx Complications of the puerperium  
 678 – 679.xx Other maternal and fetal complications  
 V202 Routine Infant/Child Health Check  
 V203 Newborn Health Supervision  
 V2031 Health Supervision Nb <8 Days  
 V2032 Health Supervision Nb 8-28 Days  
 V213 Low Birth Weight Status  
 V2130 Low Birth Weight Unspec  
 V2131 Low Birth Weight <500 Gm  
 V2132 Low Birth Weight 500-999gm  
 V2133 Low Birth Weight 1000-1499gm

|       |                                     |
|-------|-------------------------------------|
| V2134 | Low Birth Weight 1500-1999gm        |
| V2135 | Low Birth Weight 2000-2500gm        |
| V218  | Other Constit State In Development  |
| V219  | Unspec Constit State In Developmnt  |
| V24   | Postpartum Care And Examination     |
| V240  | Postpartum Care Exam After Delivery |
| V241  | Postpartum Care Lactating Mother    |
| V27   | Outcome Of Delivery                 |
| V270  | Deliver Single Liveborn             |
| V271  | Deliver Single Stillborn            |
| V272  | Deliver Twins Liveborn              |
| V273  | Delivery Twins One Stillborn        |
| V274  | Delivery Twins Both Stillborn       |
| V275  | Delivery Mult Birth All Liveborn    |
| V276  | Delivery Mult Birth Some Liveborn   |
| V277  | Delivery Mult Birth All Stillborn   |
| V279  | Outcome Of Delivery Unspec          |
| V29   | Observ Suspect Problem Newborn      |
| V290  | Infant Observation Infectious       |
| V291  | Infant Observation Neurology        |
| V292  | Infant Observation Respirat         |
| V293  | Infant Obser Genetic Cond           |
| V298  | Infant Observatn Cond Ot            |
| V299  | Infant Observatn Cond Unspec        |
| V30   | Single Liveborn                     |
| V300  | Single Liveborn Born In Hospital    |
| V3000 | Sgl Liveborn No C-Section           |
| V3001 | Sgl Liveborn W C-Section            |
| V301  | Sgl Livebrn Before Admission        |
| V302  | Sgl Liveborn Not Admitted           |
| V31   | Twin Birth Mate Liveborn            |
| V310  | Twin Birth Mate Lb In Hospital      |
| V3100 | Twin Mate In Hospital               |
| V3101 | Twin Mate C-Section                 |
| V311  | Twin Mate Before Admission          |
| V312  | Twin Mate Not Admitted              |
| V32   | Twin Birth Mate Stillborn           |
| V320  | Twin Birth Mate Sb In Hospital      |
| V3200 | Twin Mate Stillborn In Hosp         |
| V3201 | Twin Mate Stillbrn C-Section        |
| V321  | Twin Mate Stillborn Before Adm      |
| V322  | Twin Mate Stillborn Not Admit       |
| V33   | Twin Birth Unspecified              |
| V330  | Twin Unsp In Hospital               |
| V3300 | Twin Unsp In Hospital               |
| V3301 | Twin Unsp C-Section                 |
| V331  | Twin Unsp Before Admission          |
| V332  | Twin Unsp Not Admitted              |
| V34   | Ot Multiple In Hospital             |
| V340  | Ot Multiple Birth                   |
| V3400 | Ot Multiple In Hospital             |
| V3401 | Ot Multiple C-Section               |
| V341  | Ot Multiple Before Adm              |
| V342  | Ot Multiple Not Admitted            |
| V35   | Ot Multiple Stillborn               |

|       |                                   |
|-------|-----------------------------------|
| V350  | Ot Multiple Stillborn In Hosp     |
| V3500 | Ot Multiple Stillborn In Hosp     |
| V3501 | Ot Multiple Stillborn C-Section   |
| V351  | Ot Multiple Stillborn Before Adm  |
| V352  | Ot Multiple Stillborn Not Adm     |
| V36   | Multiple Live/Still Unspecified   |
| V360  | Multip Live/Still Born In Hosptal |
| V3600 | Multiple Live/Still In Hosptal Ot |
| V3601 | Multiple Live/Still By C-Section  |
| V361  | Multiple Live/Still Before Adm    |
| V362  | Multiple Live/Still Not Admitted  |
| V37   | Unspecified Multiple Birth        |
| V370  | Unspecified Multiple Birth No C-S |
| V3700 | Multiple Nb Unsp In Hosp Ot       |
| V3701 | Multiple Nb Unsp C-Section        |
| V371  | Multiple Brth Unsp Before Adm     |
| V372  | Multiple Birth Unsp Not Admit     |
| V39   | Liveborn Unspecified              |
| V390  | Liveborn In Hospital              |
| V3900 | Liveborn Unsp In Hosp             |
| V3901 | Liveborn Unsp C-Section           |
| V391  | Liveborn Unsp Before Adm          |
| V392  | Liveborn Unsp Not Admitted        |

---

End



## APPENDIX 5. SERIOUS LIVER INJURY/DISEASE BASELINE EXCLUSIONARY SCREENING

### ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions

#### History of Serious Liver Injury/Disease

##### ICD-9-CM Diagnoses

- 277.4 Disorders of bilirubin excretion
- 570 Acute and subacute necrosis of liver
- 571.5 Cirrhosis of liver without mention of alcohol
- 572.2 Hepatic coma
- 572.4 Hepatorenal syndrome
- 572.8 Other sequelae of chronic liver disease\*
- 573.0 Chronic passive congestion of liver
- 573.3 Hepatitis, unspecified
- 573.8 Other specified disorders of liver
- 573.9 Unspecified disorder of liver
- 782.4 Jaundice, unspecified
- 794.8 Nonspecific abnormal results of liver function test
- V42.7 Liver replaced by transplant

##### ICD-9-CM Procedures

- 50.11 Closed (percutaneous) [needle] biopsy of liver
- 50.12 Open biopsy of liver
- 50.13 Transjugular liver biopsy
- 50.14 Laparoscopic liver biopsy
- 50.5 Liver transplant
- 50.51 Auxiliary liver transplant
- 50.59 Other transplant of liver
- 50.91 Percutaneous aspiration of liver

##### CPT® Procedures

- 47000 Biopsy of liver, needle; percutaneous
  - 47001 Biopsy of liver, needle; done at time of other major procedure
  - 47100 Biopsy of liver, wedge
  - 47135 Liver allotransplantation; orthotopic, partial or whole
  - 47136 Liver allotransplantation; heterotopic, partial or whole
  - 78205 Liver imaging (SPECT)
  - 78206 Liver imaging (SPECT); with vascular flow
-

## **History of Viral Hepatitis**

### **ICD-9-CM Diagnoses**

070.0 Viral Hepatitis A With Hepatic Coma  
070.1 Viral Hepatitis A Without Hepatic Coma  
070.2 Viral Hepatitis B With Hepatic Coma  
070.20 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified Without Hepatitis Delta  
070.21 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified With Hepatitis Delta  
070.22 Chronic Viral Hepatitis B With Hepatic Coma Without Hepatitis Delta  
070.23 Chronic Viral Hepatitis B With Hepatic Coma With Hepatitis Delta  
070.3 Viral Hepatitis B Without Mention Of Hepatic Coma  
070.30 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified Without Hepatitis Delta  
070.31 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified With Hepatitis Delta  
070.32 Chronic Viral Hepatitis B Without Hepatic Coma Without Hepatitis Delta  
070.33 Chronic Viral Hepatitis B Without Hepatic Coma With Hepatitis Delta  
070.4 Other Specified Viral Hepatitis With Hepatic Coma  
070.41 Acute Hepatitis C With Hepatic Coma  
070.42 Hepatitis Delta Without Active Hepatitis B Disease With Hepatic Coma  
070.43 Hepatitis E With Hepatic Coma  
070.44 Chronic Hepatitis C With Hepatic Coma  
070.49 Other Specified Viral Hepatitis With Hepatic Coma  
070.5 Other Specified Viral Hepatitis Without Mention Of Hepatic Coma  
070.51 Acute Hepatitis C Without Mention Of Hepatic Coma  
070.52 Hepatitis Delta Without Active Hepatitis B Disease Or Hepatic Coma  
070.53 Hepatitis E Without Hepatic Coma  
070.54 Chronic Hepatitis C Without Hepatic Coma  
070.59 Other Specified Viral Hepatitis Without Hepatic Coma  
070.7 Unspecified Viral Hepatitis C  
070.70 Unspecified Viral Hepatitis C Without Hepatic Coma  
070.71 Unspecified Viral Hepatitis C With Hepatic Coma  
V02.61 Carrier Or Suspected Carrier Of Hepatitis B  
V02.62 Carrier Or Suspected Carrier Of Hepatitis C

---

## **Non-Specific – Other Related Hepatitis**

### **ICD-9-CM Diagnoses**

070.6 Unspecified Viral Hepatitis With Hepatic Coma  
070.9 Unspecified Viral Hepatitis Without Hepatic Coma  
072.71 Mumps Hepatitis  
091.62 Secondary Syphilitic Hepatitis  
571.4 Chronic Hepatitis  
571.40 Chronic Hepatitis, Unspecified  
571.41 Chronic Persistent Hepatitis  
571.42 Autoimmune Hepatitis  
571.49 Other Chronic Hepatitis  
571.8 Other Chronic Nonalcoholic Liver Disease

572.0 Abscess of Liver  
V02.6 Carrier Or Suspected Carrier Of Viral Hepatitis  
V02.60 Carrier Or Suspected Carrier Of Viral Hepatitis Unspecified  
V02.69 Carrier Or Suspected Carrier Of Other Viral Hepatitis

---

### **History of Hereditary Conditions**

#### **ICD-9-CM Diagnoses**

271.0 Glycogenosis  
271.1 Galactosemia  
273.4 Alpha-1-Antitrypsin Deficiency  
275.0 Disorders Of Iron Metabolism  
275.01 Hereditary Hemochromatosis  
275.03 Other Hemochromatosis  
275.1 Disorders Of Copper Metabolism  
759.89 Other Specified Congenital Anomalies (Alagille syndrome)

---

End





## **APPENDIX 6. INTERSTITIAL LUNG DISEASE - NARROW DEFINITION; BASELINE EXCLUSIONARY SCREENING**

### **ICD-9-CM Code Descriptions**

#### **History of Interstitial Lung Disease**

- 515 Post-inflammatory pulmonary fibrosis
  - 516.3 Idiopathic fibrosing alveolitis
  - 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
  - 516.31 Idiopathic pulmonary fibrosis (IPF)
  - 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
  - 516.33 Acute interstitial pneumonitis (AIP)
  - 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
  - 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
  - 516.36 Cryptogenic organizing pneumonia (COP)
  - 516.37 Desquamative interstitial pneumonia (DIP)
  - 516.8 Other specified alveolar and parietoalveolar pneumonopathies
  - 516.9 Unspecified alveolar and parietoalveolar pneumonopathy
- 

#### **History of Pneumonia**

- 480 Viral Pneumonia
- 480.0 Pneumonia Due To Adenovirus
- 480.1 Pneumonia Due To Respiratory Syncytial Virus
- 480.2 Pneumonia Due To Parainfluenza Virus
- 480.3 Pneumonia Due To Sars-Associated Coronavirus
- 480.8 Pneumonia Due To Other Virus Not Elsewhere Classified
- 480.9 Viral Pneumonia Unspecified
- 481 Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia]
- 482 Other Bacterial Pneumonia
- 482.0 Pneumonia Due To Klebsiella Pneumoniae
- 482.1 Pneumonia Due To Pseudomonas
- 482.2 Pneumonia Due To Hemophilus Influenzae (H. Influenzae)
- 482.3 Pneumonia Due To Streptococcus
- 482.30 Pneumonia Due To Streptococcus Unspecified
- 482.31 Pneumonia Due To Streptococcus Group A
- 482.32 Pneumonia Due To Streptococcus Group B
- 482.39 Pneumonia Due To Other Streptococcus
- 482.4 Pneumonia Due To Staphylococcus
- 482.40 Pneumonia Due To Staphylococcus Unspecified
- 482.41 Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus
- 482.42 Methicillin Resistant Pneumonia Due To Staphylococcus Aureus
- 482.49 Other Staphylococcus Pneumonia
- 482.8 Pneumonia Due To Other Specified Bacteria
- 482.81 Pneumonia Due To Anaerobes
- 482.82 Pneumonia Due To Escherichia Coli [E.Coli]
- 482.83 Pneumonia Due To Other Gram-Negative Bacteria

482.84 Pneumonia Due To Legionnaires' Disease  
482.89 Pneumonia Due To Other Specified Bacteria  
482.9 Bacterial Pneumonia Unspecified  
483.8 Pneumonia Due To Other Specified Organism  
485 Bronchopneumonia Organism Unspecified  
486 Pneumonia Organism Unspecified  
487.0 Influenza With Pneumonia  
507.0 Pneumonitis due to inhalation of food or vomitus  
V12.61 Personal History Of Pneumonia (Recurrent)

---

## **History of Sarcoidosis**

135 Sarcoidosis

---

End

## APPENDIX 7. TREATMENT EPISODE AND FOLLOW-UP IDENTIFICATION PERIOD

Figure 1. SLD Index Treatment Episode / Follow-up Period Examples

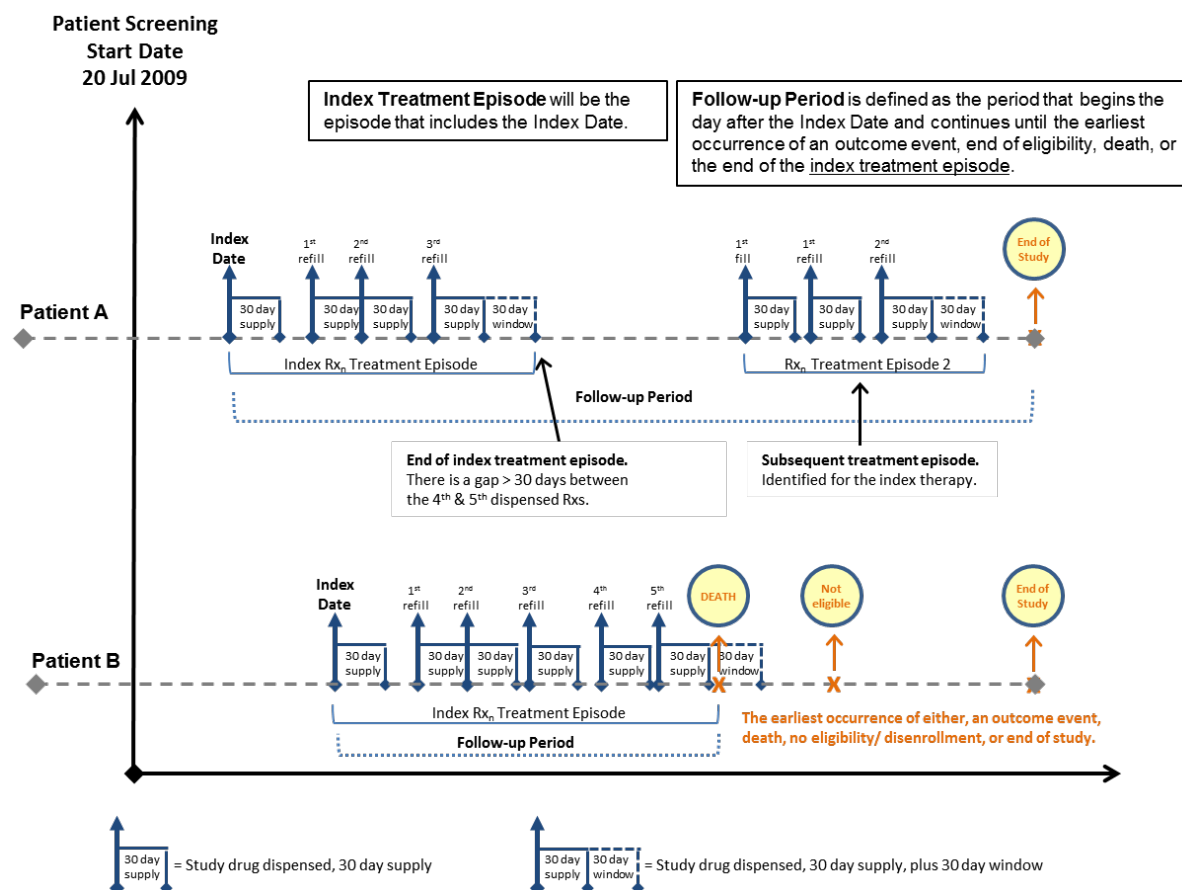
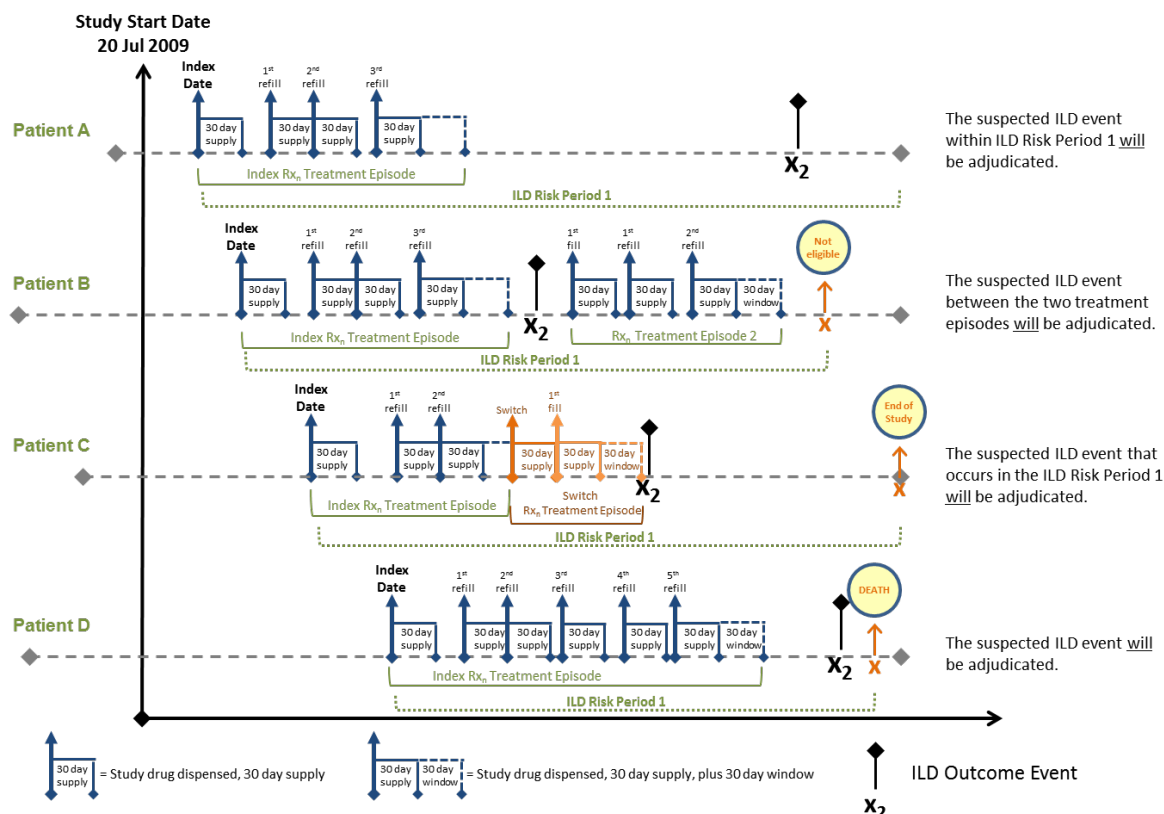


**Figure 2. Identifying Patients with Suspected ILD Outcome Events during ILD Risk Period 1 for Adjudication**



## APPENDIX 8. SERIOUS LIVER INJURY/DISEASE OUTCOME EVENT DEFINITION

### ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions

#### **ICD-9-CM Diagnoses**

|       |                                                     |
|-------|-----------------------------------------------------|
| 277.4 | Disorders of bilirubin excretion                    |
| 570   | Acute and subacute necrosis of liver                |
| 571.5 | Cirrhosis of liver without mention of alcohol       |
| 572.2 | Hepatic coma                                        |
| 572.4 | Hepatorenal syndrome                                |
| 572.8 | Other sequelae of chronic liver disease*            |
| 573.0 | Chronic passive congestion of liver                 |
| 573.3 | Hepatitis, unspecified                              |
| 573.8 | Other specified disorders of liver                  |
| 573.9 | Unspecified disorder of liver                       |
| 782.4 | Jaundice, unspecified                               |
| 794.8 | Nonspecific abnormal results of liver function test |
| V42.7 | Liver replaced by transplant                        |

#### **ICD-9-CM Procedures**

|       |                                                |
|-------|------------------------------------------------|
| 50.11 | Closed (percutaneous) [needle] biopsy of liver |
| 50.12 | Open biopsy of liver                           |
| 50.13 | Transjugular liver biopsy                      |
| 50.14 | Laparoscopic liver biopsy                      |
| 50.5  | Liver transplant                               |
| 50.51 | Auxiliary liver transplant                     |
| 50.59 | Other transplant of liver                      |
| 50.91 | Percutaneous aspiration of liver               |

#### **CPT® Procedures**

|       |                                                                |
|-------|----------------------------------------------------------------|
| 47000 | Biopsy of liver, needle; percutaneous                          |
| 47001 | Biopsy of liver, needle; done at time of other major procedure |
| 47100 | Biopsy of liver, wedge                                         |
| 47135 | Liver allotransplantation; orthotopic, partial or whole        |
| 47136 | Liver allotransplantation; heterotopic, partial or whole       |
| 78205 | Liver imaging (SPECT)                                          |
| 78206 | Liver imaging (SPECT); with vascular flow                      |

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\* Approved for definition inclusion on October 22, 2013 by Epi Steering Committee.

Also approved for removal from the definition were two diagnosis codes:

789.1 Hepatomegaly, and  
791.4 Biliuria

## SLD OUTCOME EVENT DEFINITION - GROUP A CODES

### Group A Codes (usually reflects Liver Injury/Disease)

#### ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions

##### **ICD-9-CM Diagnosis** (may occur in any code position; inpatient setting):

570 Acute and subacute necrosis of liver  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
V42.7 Liver replaced by transplant

##### **ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver

##### **CPT®** (may occur in any code position; inpatient setting):

47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole

---

## SLD OUTCOME EVENT DEFINITION - GROUP B CODES

### Group B Codes (highly suspicious, suggestive of Liver Injury/Disease)

#### ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions

**ICD-9-CM Diagnosis** (diagnosis must be an inpatient primary discharge diagnosis):

|       |                                                     |
|-------|-----------------------------------------------------|
| 277.4 | Disorders of bilirubin excretion                    |
| 571.5 | Cirrhosis of liver without mention of alcohol       |
| 572.8 | Other sequelae of chronic liver disease*            |
| 573.0 | Chronic passive congestion of liver                 |
| 573.3 | Hepatitis, unspecified                              |
| 573.8 | Other specified disorders of liver                  |
| 573.9 | Unspecified disorder of liver                       |
| 782.4 | Jaundice, unspecified                               |
| 794.8 | Nonspecific abnormal results of liver function test |

**ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

|       |                                                |
|-------|------------------------------------------------|
| 50.11 | Closed (percutaneous) [needle] biopsy of liver |
| 50.12 | Open biopsy of liver                           |
| 50.13 | Transjugular liver biopsy                      |
| 50.14 | Laparoscopic liver biopsy                      |
| 50.91 | Percutaneous aspiration of liver               |

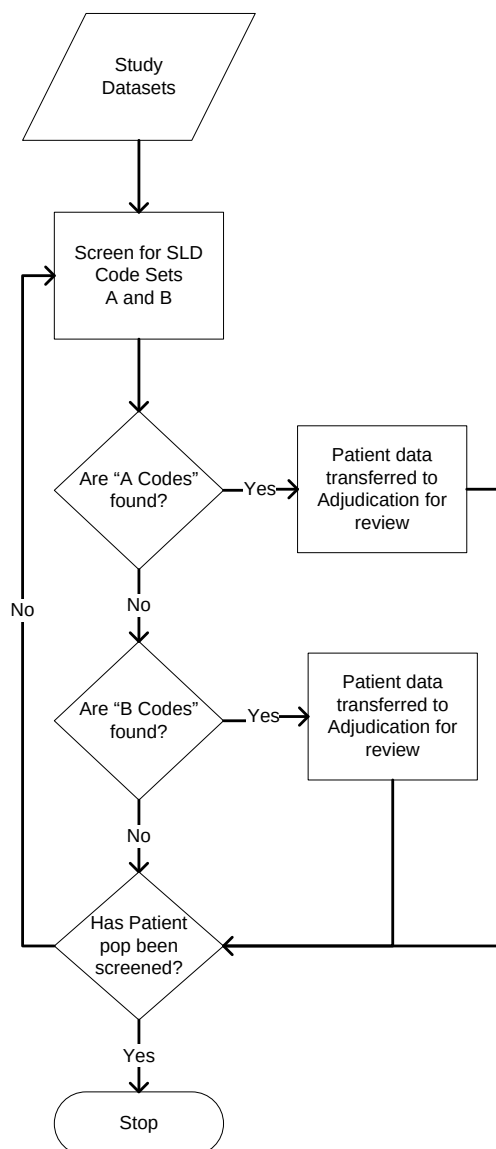
**CPT®** (may occur in any code position; inpatient setting):

|       |                                                                |
|-------|----------------------------------------------------------------|
| 47000 | Biopsy of liver, needle; percutaneous                          |
| 47001 | Biopsy of liver, needle; done at time of other major procedure |
| 47100 | Biopsy of liver, wedge                                         |
| 78205 | Liver imaging (SPECT)                                          |
| 78206 | Liver imaging (SPECT); with vascular flow                      |

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\* Approved for definition inclusion on October 22, 2013.

## ALGORITHM FOR SELECTION OF SLD OUTCOME EVENTS FOR ADJUDICATION



### A CODES

**ICD-9-CM Diagnosis (may occur in any code position; inpatient setting)**

570 Acute and subacute necrosis of liver  
 572.2 Hepatic coma  
 572.4 Hepatorenal syndrome  
 V42.7 Liver replaced by transplant

**ICD-9-CM Procedures (may occur in any code position; inpatient setting)**

50.5 Liver transplant  
 50.51 Auxiliary liver transplant  
 50.59 Other transplant of liver

**CPT (may occur in any code position; inpatient setting)**

47135 Liver allotransplantation; orthotopic, partial or whole  
 47136 Liver allotransplantation; heterotopic, partial or whole

### B CODES

**ICD-9-CM Diagnosis (must be a primary discharge diagnosis)**

277.4 Disorders of bilirubin excretion  
 571.5 Cirrhosis of liver without mention of alcohol  
 572.8 Other sequelae of chronic liver disease  
 573.0 Chronic passive congestion of liver  
 573.3 Hepatitis, unspecified  
 573.8 Other specified disorders of liver  
 573.9 Unspecified disorder of liver  
 782.4 Jaundice, unspecified  
 794.8 Nonspecific abnormal results of liver function test

**ICD-9-CM Procedures (may occur in any code position; inpatient setting)**

50.11 Closed (percutaneous) [needle] biopsy of liver  
 50.12 Open biopsy of liver  
 50.13 Transjugular liver biopsy  
 50.14 Laparoscopic liver biopsy  
 50.91 Percutaneous aspiration of liver

**CPT (may occur in any code position; inpatient setting)**

47000 Biopsy of liver, needle; percutaneous  
 47001 Biopsy of liver, needle; done at time of other major procedure  
 47100 Biopsy of liver, wedge  
 78205 Liver imaging (SPECT)  
 78206 Liver imaging (SPECT); with vascular flow



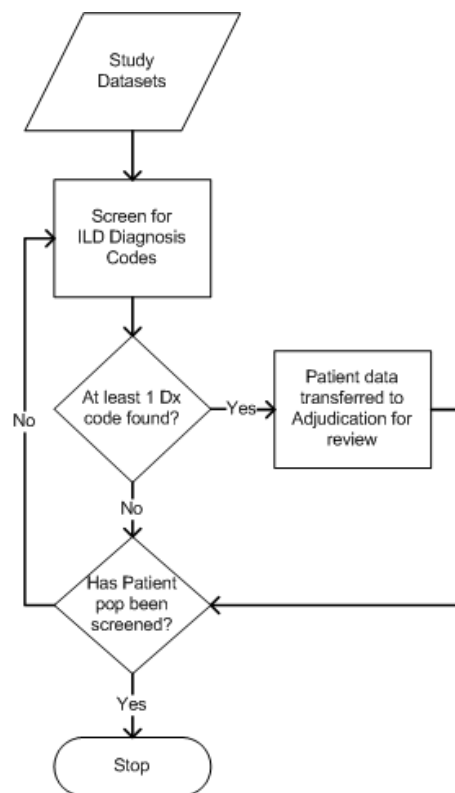
## APPENDIX 9. ILD OUTCOME EVENT - NARROW DEFINITION

### ICD-9-CM Diagnosis Codes (Codes must be an inpatient discharge diagnosis)

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

---

## ALGORITHM FOR SELECTION OF SUSPECTED ILD (NARROW) OUTCOME EVENTS FOR ADJUDICATION



Code occurrence must be among the hospital discharge diagnoses.

### ICD-9-CM

| Code   | Description                                                      |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

## APPENDIX 10. LIVER INJURY/DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Codes to identify patients with pre-existing liver/biliary diseases, and chronic liver disease.

| ICD-9-CM | Diagnosis Code Description |
|----------|----------------------------|
|----------|----------------------------|

### History of Alcoholism

|       |                                    |
|-------|------------------------------------|
| 571.0 | Alcoholic Fatty Liver              |
| 571.1 | Acute Alcoholic Hepatitis          |
| 571.2 | Alcoholic Cirrhosis Of Liver       |
| 571.3 | Unspecified Alcoholic Liver Damage |

### History of Biliary Duct Disorders

|        |                                                                                      |
|--------|--------------------------------------------------------------------------------------|
| 574.00 | Calculus Of Gallbladder With Acute Cholecystitis Without Obstruction                 |
| 574.01 | Calculus Of Gallbladder With Acute Cholecystitis With Obstruction                    |
| 574.10 | Calculus Of Gallbladder With Other Cholecystitis Without Obstruction                 |
| 574.11 | Calculus Of Gallbladder With Other Cholecystitis With Obstruction                    |
| 574.20 | Calculus Of Gallbladder Without Cholecystitis Without Obstruction                    |
| 574.21 | Calculus Of Gallbladder Without Cholecystitis With Obstruction                       |
| 574.30 | Calculus Of Bile Duct With Acute Cholecystitis Without Obstruction                   |
| 574.31 | Calculus Of Bile Duct With Acute Cholecystitis With Obstruction                      |
| 574.40 | Calculus Of Bile Duct With Other Cholecystitis                                       |
| 574.41 | Calculus Of Bile Duct With Other Cholecystitis Without Obstruction                   |
| 574.50 | Calculus Of Bile Duct With Other Cholecystitis With Obstruction                      |
| 574.51 | Calculus Of Bile Duct Without Mention Of Cholecystitis                               |
| 574.60 | Calculus Of Bile Duct Without Cholecystitis Without Obstruction                      |
| 574.61 | Calculus Of Bile Duct Without Cholecystitis With Obstruction                         |
| 574.70 | Calculus Of Gallbladder And Bile Duct With Acute Cholecystitis                       |
| 574.71 | Calculus Of Gallbladder And Bile Duct With Other Cholecystitis, With Obstruction     |
| 574.80 | Calculus Of Gallbladder And Bile Duct W Acute& Chronic Cholecystitis W/o Obstruction |
| 574.81 | Calculus Of Gallbladder And Bile Duct W Acute & Chronic Cholecystitis W/Obstruction  |
| 574.90 | Calculus Of Gallbladder And Bile Duct Without Cholecystitis Without Obstruction      |
| 574.91 | Calculus Of Gallbladder And Bile Duct Without Cholecystitis With Obstruction         |
| 575.0  | Acute Cholecystitis                                                                  |
| 575.1  | Other Cholecystitis                                                                  |
| 575.10 | Cholecystitis Unspecified                                                            |
| 575.11 | Chronic Cholecystitis                                                                |
| 575.12 | Acute And Chronic Cholecystitis                                                      |
| 575.2  | Obstruction Of Gallbladder                                                           |
| 575.3  | Hydrops Of Gallbladder                                                               |
| 575.4  | Perforation Of Gallbladder                                                           |
| 575.5  | Fistula Of Gallbladder                                                               |
| 575.6  | Cholesterolosis Of Gallbladder                                                       |
| 575.8  | Other Specified Disorders Of Gallbladder                                             |
| 575.9  | Unspecified Disorder Of Gallbladder                                                  |
| 576.1  | Cholangitis                                                                          |

### History of Congestive Heart Failure

|       |                                      |
|-------|--------------------------------------|
| 428   | Heart Failure                        |
| 428.0 | Congestive Heart Failure Unspecified |
| 428.1 | Left Heart Failure                   |

|        |                                                                |
|--------|----------------------------------------------------------------|
| 428.2  | Systolic Heart Failure                                         |
| 428.20 | Unspecified Systolic Heart Failure                             |
| 428.21 | Acute Systolic Heart Failure                                   |
| 428.22 | Chronic Systolic Heart Failure                                 |
| 428.23 | Acute On Chronic Systolic Heart Failure                        |
| 428.3  | Diastolic Heart Failure                                        |
| 428.30 | Unspecified Diastolic Heart Failure                            |
| 428.31 | Acute Diastolic Heart Failure                                  |
| 428.32 | Chronic Diastolic Heart Failure                                |
| 428.33 | Acute On Chronic Diastolic Heart Failure                       |
| 428.4  | Combined Systolic And Diastolic Heart Failure                  |
| 428.40 | Unspecified Combined Systolic And Diastolic Heart Failure      |
| 428.41 | Acute Combined Systolic And Diastolic Heart Failure            |
| 428.42 | Chronic Combined Systolic And Diastolic Heart Failure          |
| 428.43 | Acute On Chronic Combined Systolic And Diastolic Heart Failure |
| 428.9  | Heart Failure Unspecified                                      |

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### History of Diabetes

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|        |                                                               |
|--------|---------------------------------------------------------------|
| 250.xx | Diabetes Mellitus                                             |
| V18.0  | Family History Of Diabetes Mellitus                           |
| V18.1  | Family History Of Other Endocrine And Metabolic Diseases      |
| V18.11 | Family History Of Multiple Endocrine Neoplasia [Men] Syndrome |
| V18.19 | Family History Of Other Endocrine And Metabolic Diseases      |

**Medication Proxy** (Occurrence of medication prior to index date) [from Facts & Comparisons eAnswers – Antidiabetic Agents, accessed April 6, 2015.]

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acarbose  
 albiglutide  
 alogliptin  
 bromocriptine  
 canagliflozin  
 chlorpropamide  
 dapagliflozin  
 dulaglutide  
 empagliflozin  
 exenatide  
 glimepiride  
 glipizide  
 glyburide ( glibenclamide)  
 insulin aspart  
 insulin detemir  
 insulin glargine (rdna origin)  
 insulin glulisine  
 insulin isophane ( nph)  
 insulin isophane (nph) /insulin regular  
 insulin lispro  
 insulin regular  
 linagliptin  
 liraglutide  
 metformin hydrochloride  
 miglitol  
 nateglinide  
 pioglitazone  
 pramlintide  
 repaglinide  
 rosiglitazone  
 saxagliptin  
 sitagliptin  
 tolazamide

tolbutamide  
 alogliptin/metformin hydrochloride  
 alogliptin/pioglitazone  
 canagliflozin/metformin hydrochloride  
 dapagliflozin/metformin  
 empagliflozin/linagliptin  
 glipizide/metformin hydrochloride  
 glyburide/metformin hydrochloride  
 linagliptin/metformin hydrochloride  
 pioglitazone/glimepiride  
 pioglitazone/metformin hydrochloride  
 repaglinide/metformin hydrochloride  
 rosiglitazone/glimepiride  
 rosiglitazone/metformin hydrochloride  
 saxagliptin/metformin hydrochloride  
 sitagliptin/metformin hydrochloride  
 sitagliptin/simvastatin

### History of Obesity

|        |                                                 |
|--------|-------------------------------------------------|
| 278    | Overweight, Obesity And Other Hyperalimentation |
| 278.0  | Overweight And Obesity                          |
| 278.00 | Obesity Unspecified                             |
| 278.01 | Morbid Obesity                                  |
| 278.02 | Overweight                                      |
| 278.03 | Obesity Hypoventilation Syndrome                |
| V85.41 | BMI 40.0 – 44.9, adult                          |
| V85.42 | BMI 45.0 – 49.9, adult                          |
| V85.43 | BMI 50.0 – 59.9, adult                          |
| V85.44 | BMI 60.0 – 69.9, adult                          |
| V85.45 | BMI 70 and over, adult                          |

### Other Anti-arrhythmic Agents (Therapeutic class # 240404\*)

|                                            |                             |
|--------------------------------------------|-----------------------------|
| Bretylum Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylum Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride           | Quinidine Polygalacturonate |
| Disopyramide Phosphate                     | Quinidine Sulfate           |
| Lidocaine Hydrochloride                    | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                   |                             |

\* Systemic use; screen for only the agents list above.

### Hepatotoxic Medications

| Generic Name (Alias)                         | Product Name                                                                 |
|----------------------------------------------|------------------------------------------------------------------------------|
| Study Period: 7/20/2008 to 9/30/2014         |                                                                              |
| Acetaminophen (N-Acetyl-P-Aminophenol; APAP) | Acetaminophen<br>Children's Tylenol<br>Children's Q-PAP<br>Genapap<br>Genebs |

|                                                                  |                                                    |
|------------------------------------------------------------------|----------------------------------------------------|
|                                                                  | Mapap                                              |
|                                                                  | Mapap Arthritis Pain                               |
|                                                                  | Pain & Fever                                       |
|                                                                  | Pain Relief                                        |
|                                                                  | Pain Relief Extra Strength                         |
|                                                                  | Pain Reliever                                      |
|                                                                  | Q-PAP                                              |
|                                                                  | Sedapap                                            |
|                                                                  | Tylenol 8 Hour                                     |
|                                                                  | Tylenol Cold                                       |
|                                                                  | Tylenol Extra Strength                             |
|                                                                  | Tylenol                                            |
| <b>Acetaminophen in Combination Products</b>                     |                                                    |
| <i>Acetaminophen/Aspirin/Caffeine/Codeine</i>                    | <i>Acetaminophen/Aspirin/Caffeine/ Codeine</i>     |
| Acetaminophen/Aspirin/Caffeine/Salicylamide                      | Levacet                                            |
| Acetaminophen/Atropine/Caffeine/Ephedrine                        | Acetaminophen/Atropine/Caffeine/Ephedrine          |
| Acetaminophen/Caffeine/Dihydrocodeine Bitartrate                 | Acetaminophen/ Caffeine/ Dihydrocodeine Bitartrate |
|                                                                  | Trezix                                             |
| Acetaminophen/Butalbital                                         | BUPAP                                              |
|                                                                  | Cephadyn                                           |
|                                                                  | Sedapap                                            |
|                                                                  | Phrenilin Forte                                    |
| Acetaminophen/Butalbital/Caffeine                                | Acetaminophen/Butalbital/Caffeine                  |
|                                                                  | Dolgic Plus                                        |
|                                                                  | Esgic                                              |
|                                                                  | Esgic-Plus                                         |
|                                                                  | Fioricet                                           |
|                                                                  | Zebutal                                            |
| Acetaminophen/Butalbital/Codeine Phosphate                       | Acetaminophen/Butalbital/Codeine Phosphate         |
| Acetaminophen/Butalbital/Caffeine/Codeine                        | Acetaminophen/ Butalbital /Caffeine/Codeine        |
|                                                                  | Fioricet with Codeine                              |
| Acetaminophen/Caffeine/ Parylamine                               | Midol Maximum Strength Menstrual                   |
| Acetaminophen/Calcium Carbonate                                  | Various                                            |
| Acetaminophen/Codeine Phosphate                                  | Acetaminophen/Codeine Phosphate                    |
|                                                                  | Tylenol with Codeine #3                            |
| Acetaminophen/Dextromethorphan/Diphenhydramine/<br>Phenylephrine | Respa C&C                                          |
|                                                                  | Respa C&C IR                                       |
| Acetaminophen/Dextromethorphan                                   | Various                                            |
| Acetaminophen/Guaifenesin                                        | Various                                            |
| Acetaminophen/ Hydrocodone Bitartrate                            | Acetaminophen/ Hydrocodone Bitartrate              |
|                                                                  | Hycet                                              |
|                                                                  | Lorcet                                             |
|                                                                  | Lortab                                             |
|                                                                  | Norco                                              |
|                                                                  | Stagesic                                           |
|                                                                  | Vicodin                                            |
|                                                                  | Vicodin ES                                         |
|                                                                  | Vicodin HP                                         |
|                                                                  | Xodol 5-300                                        |
|                                                                  | Xodol 10-300                                       |
|                                                                  | Zamicet                                            |
|                                                                  | Zydone                                             |
| Acetaminophen/Isometheptene Mucate/Caffeine                      | Acetaminophen/Isometheptene Mucate/Caffeine        |
|                                                                  | Prodrin                                            |
| Acetaminophen /Isometheptene/Dichloralphenazone                  | Acetaminophen/Isometheptene/Dichloralphenazone     |
|                                                                  | Diacetazone                                        |
|                                                                  | Epidrin                                            |
|                                                                  | I.D.A.                                             |
|                                                                  | Midrin                                             |

|                                                                                                        |                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acetaminophen/Oxycodone HCL                                                                            | Migquin<br>Migratine<br>Migrazone<br>Acetaminophen/Oxycodone HCL<br>Endocet<br>Magnacet<br>Percocet<br>Roxicet<br>Tylox<br>Xolox                       |
| Acetaminophen/Pentazocine                                                                              | Acetaminophen/Pentazocine<br>Talacen                                                                                                                   |
| Acetaminophen/Pheniramine/Phenylephrine<br>Acetaminophen/Doxylamine/Phenylephrine/<br>Dextromethorphan | Various<br>Various                                                                                                                                     |
| Acetaminophen/Phenylephrine<br>Acetaminophen/Phenyltoloxamine                                          | Various<br>Dologesic<br>Flextra-650<br>Relagesic<br>POLY-650<br>RhinoFlex-650                                                                          |
| Acetaminophen/Phenyltoloxamine/Salicylamide                                                            | Ed-Flex<br>Dolorex                                                                                                                                     |
| Acetaminophen/Propoxyphene HCL<br>Acetaminophen/Propoxyphene Napsylate                                 | Propoxyphene HCL /Acetaminophen<br>Propoxyphene Napsylate/Acetaminophen<br>Balacet 325<br>Darvocet A500<br>Darvocet-N 100<br>Darvocet-N 50<br>Propacet |
| Acetaminophen/ Tramadol HCL                                                                            | Tramadol HCL/Acetaminophen<br>Ultracet                                                                                                                 |
| <b>Acitretin</b>                                                                                       | Acitretin<br>Soriatane                                                                                                                                 |
| <b>Allopurinol</b>                                                                                     | Allopurinol<br>Aloprim<br>Lopurin<br>Zyloprim                                                                                                          |
| <b>Amitriptyline</b>                                                                                   | Amitriptyline<br>Amitid<br>Amitril<br>Elavil<br>Endep                                                                                                  |
| Amitriptyline HCL/Chlordiazepoxide                                                                     | Amitriptyline HCL/Chlordiazepoxide<br>Limbitrol<br>Limbitrol DS                                                                                        |
| Amitriptyline HCL/Perphenazine                                                                         | Amitriptyline HCL/Perphenazine<br>Etrafon<br>Etrafon A<br>Etrafon Forte<br>Triavil                                                                     |
| <b>Amoxicillin/Potassium Clavulanate</b>                                                               | Amoxicillin-Pot Clavulanate<br>Augmentin<br>Augmentin ES 600<br>Augmentin XR                                                                           |
| <b>Asparaginase Erwinia Chrysanthemi</b>                                                               | Erwinaze                                                                                                                                               |
| <b>Azathioprine</b>                                                                                    | Azathioprine<br>Azasan<br>Imuran                                                                                                                       |
| <b>Baclofen</b>                                                                                        | Baclofen                                                                                                                                               |

|                                                       |                                                                                                           |
|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|                                                       | Gablofen<br>Kemstro<br>Lioresal                                                                           |
| <b>Bosentan</b>                                       | Tracleer                                                                                                  |
| <b>Ciprofloxacin</b>                                  | Ciprofloxacin<br>Cipro<br>Cipro XR<br>Proquin XR                                                          |
| <b>Clindamycin</b>                                    | Clindamycin Phosphate<br>Clindamycin HCL<br>Clindamycin Palmitate HCl<br>Cleocin                          |
| <b>Chlorpromazine HCL</b>                             | Chlorpromazine<br>Chlorpromazine Intensol<br>Promapar<br>Sonazine<br>Thorazine                            |
| <b>Cyclophosphamide</b>                               | Cyclophosphamide<br>Cytosan<br>Cytosan Lyophilized<br>Lyophilized Cytosan<br>Neosar                       |
| <b>Cytarabine</b>                                     | Cytarabine<br>Cytosar-U<br>Depocyt                                                                        |
| <b>Danazol</b>                                        | Danazol<br>Danocrine                                                                                      |
| <b>Dantrolene Sodium</b>                              | Dantrium<br>Dantrolene Sodium<br>Revonto                                                                  |
|                                                       | Ryanodex                                                                                                  |
| <b>Dapsone</b>                                        | Dapsone                                                                                                   |
| <b>Deferasirox</b>                                    | Deferasirox<br>Exjade<br>Jadenu                                                                           |
| <b>Desflurane</b>                                     | Suprane                                                                                                   |
| <b>Diclofenac</b>                                     | Zorvolex                                                                                                  |
| Diclofenac Sodium                                     | Diclofenac Sodium<br>DSG Pak<br>Dyloject<br>Pennsaid<br>Rexaphenac<br>Solaraze<br>Voltaren<br>Voltaren-XR |
| Diclofenac Potassium                                  | Cambia<br>Cataflam<br>Diclofenac Potassium<br>Zipsor                                                      |
| Diclofenac Epolamine<br>Diclofenac Sodium/Misoprostol | Flector<br>Arthrotec<br>Diclofenac Sodium/Misoprostol                                                     |
| <b>Disulfiram</b>                                     | Antabuse<br>Disulfiram                                                                                    |
| <b>Eltrombopag Olamine</b>                            | Promacta                                                                                                  |
| <b>Enflurane</b>                                      | Enflurane<br>Ethrane<br>Compound 347                                                                      |
| <b>Erythromycin Estolate</b>                          | Erythromycin Estolate                                                                                     |



|                                                     |                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Erythromycin Estolate/Sulfisoxazole Acetyl          | Ilosone<br>Ilosone Sulfa                                                                                                                                                                                                                                                                                        |
| <b>Felbamate</b>                                    | Felbamate<br>Felbatol                                                                                                                                                                                                                                                                                           |
| <b>Fenofibrate</b>                                  |                                                                                                                                                                                                                                                                                                                 |
| Choline Fenofibrate                                 | Fenofibric acid<br>Trilipix                                                                                                                                                                                                                                                                                     |
| Fenofibrate                                         | Fenofibrate<br>Lipidil<br>Fenoglide<br>Lipofen<br>Lofibra<br>Tricor<br>Triglide                                                                                                                                                                                                                                 |
| Fenofibrate micronized                              | Antara (micronized)<br>Fenofibrate micronized<br>Tricor (micronized)                                                                                                                                                                                                                                            |
| <b>Fluconazole</b>                                  | Fluconazole<br>Diflucan                                                                                                                                                                                                                                                                                         |
| <b>Flutamide</b>                                    | Flutamide                                                                                                                                                                                                                                                                                                       |
| <b>Fluvastatin</b>                                  | Fluvastatin                                                                                                                                                                                                                                                                                                     |
| Fluvastatin Sodium                                  | Fluvastatin Sodium<br>Lescol<br>Lescol XL                                                                                                                                                                                                                                                                       |
| <b>Gemfibrozil</b>                                  | Gemfibrozil<br>Lopid                                                                                                                                                                                                                                                                                            |
| <b>Halothane</b>                                    | Halothane<br>Fluothane                                                                                                                                                                                                                                                                                          |
| <b>Hydralazine HCL</b>                              | Hydralazine<br>Dralzine<br>Apresoline<br>Apresazide<br>Apresoline-Esidrix<br>Hydra-Zide<br>Hydralazine/Hydrochlorothiazide<br>BiDil<br>Cam-Ap-Es<br>Hydralazine/Hydrochlorothiazide/Reserpine<br>Hydrap-ES<br>Hydroserpine plus (r-h-h)<br>SER-A-GEN<br>SER-AP-ES<br>Unipres<br>Dralserp<br>Serpasil-Apresoline |
| Hydralazine/Hydrochlorothiazide                     |                                                                                                                                                                                                                                                                                                                 |
| Hydralazine/Isosorbide Dinitrate                    |                                                                                                                                                                                                                                                                                                                 |
| Hydralazine/Hydrochlorothiazide/Reserpine           |                                                                                                                                                                                                                                                                                                                 |
| Hydralazine/Reserpine                               |                                                                                                                                                                                                                                                                                                                 |
| <b>Infliximab</b>                                   | Remicade                                                                                                                                                                                                                                                                                                        |
| <b>Interferon beta-1a</b>                           | Avonex<br>Rebif<br>Plegridy                                                                                                                                                                                                                                                                                     |
| Peginterferon Beta-1a                               |                                                                                                                                                                                                                                                                                                                 |
| <b>Irinotecan HCL</b>                               | Camptosar<br>Irinotecan<br>Onivyde                                                                                                                                                                                                                                                                              |
| <b>Isoflurane</b>                                   | Isoflurane<br>Forane<br>Terrell                                                                                                                                                                                                                                                                                 |
| <b>Isoniazid (Isonicotinic acid hydrazide; INH)</b> | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid                                                                                                                                                                                                                                                          |

|                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Isoniazid/Rifampin                                                                                     | Nydrazid<br>Rimifon<br>Stanozide<br>Rifamate<br>Isoniazid/Rifampin                                                                                                                                                                                                                                                                                                                   |
| Isoniazid/Pyrazinamide/Rifampin                                                                        | Rifater                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Isotretinoin</b>                                                                                    | Absorica<br>Accutane<br>Amnesteem<br>Claravis<br>Myorisan<br>Sortet<br>Zenatane                                                                                                                                                                                                                                                                                                      |
| <b>Ketoconazole</b>                                                                                    | Ketoconazole                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Labetalol HCL</b>                                                                                   | Labetalol HCL<br>Normodyne<br>Trandate<br>Normozide<br>Trandate HCT                                                                                                                                                                                                                                                                                                                  |
| Labetalol HCL/Hydrochlorothiazide                                                                      |                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Lapatinib</b><br>Lapatinib Ditosylate                                                               | Lapatinib<br>Tykerb                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Leflunomide</b>                                                                                     | Leflunomide<br>Arava                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Mercaptopurine (6-Mercaptopurine; 6-MP)</b>                                                         | Mercaptopurine<br>Purinethol<br>Purixan                                                                                                                                                                                                                                                                                                                                              |
| <b>Methyltestosterone</b>                                                                              | Android 10<br>Metandren<br>Methyltestosterone<br>Oreton<br>Oreton Methyl<br>Testred<br>Virilon<br>Covaryx<br>Covaryx HS<br>EEMT<br>EEMT HS<br>Esterified Estrogens/Methyltestosterone<br>Esterified Estrogens/Methyltestosterone DS<br>Esterified Estrogens/Methyltestosterone HS<br>Premarin with Methyltestosterone<br>Conjugated Estrogen /Methyltestosterone<br>/Methamphetamine |
| Methyltestosterone/Esterified Estrogens                                                                |                                                                                                                                                                                                                                                                                                                                                                                      |
| Conjugated Estrogens/Methyltestosterone<br>Conjugated Estrogen /Methyltestosterone<br>/Methamphetamine |                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Methotrexate (Amethopterin; MTX)</b>                                                                | Methotrexate<br>Abitrexate<br>Folex PFS<br>Mexate-AQ Preserved<br>Mexate<br>Rheumatrex Dose Pack<br>Otrexup<br>Rasuvo<br>Trexall                                                                                                                                                                                                                                                     |
| <b>Methyldopa</b>                                                                                      | Methyldopa<br>Aldomet<br>Methyldopate<br>Aldoclor<br>Methyldopa/Chlorothiazide<br>Aldoril<br>Methyldopa/Hydrochlorothiazide                                                                                                                                                                                                                                                          |
| Methyldopate HCL<br>Methyldopa/Chlorothiazide                                                          |                                                                                                                                                                                                                                                                                                                                                                                      |
| Methyldopa/Hydrochlorothiazide                                                                         |                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Minocycline</b>                                                                                     | Minocycline                                                                                                                                                                                                                                                                                                                                                                          |

|                               |                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                                                                                                                                                                                                                                                                                                                                           |
| <b>Natalizumab</b>            | Tysabri                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Nitrofurantoin</b>         | Furadantin<br>Furalan<br>Nitrofurantoin<br>Ivadantin<br>Nitrofurantoin Macrocrystal<br>Macrochantin<br>Nitrofurantoin Monohydrate/Macrocrystals<br>Macrobid                                                                                                                                                                                                                                  |
|                               |                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Oxandrolone</b>            | Oxandrolone<br>Oxandrin                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Oxymetholone</b>           | Anadrol-50                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Pazopanib HCL</b>          | Votrient                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Phenytoin</b>              | Phenytoin<br>Dilantin<br>Phenytoin Sodium<br>Dilantin<br>Phenytek<br>Phenytek<br>Phenytoin Sodium Prompt<br>Fosphenytoin Sodium<br>Cerebyx<br>Mephentytoin Sodium                                                                                                                                                                                                                            |
|                               |                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Propylthiouracil (PTU)</b> | Propylthiouracil                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Sulindac</b>               | Sulindac<br>Clinoril                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Telithromycin</b>          | Ketek                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Testosterone</b>           | Androderm<br>Androgel<br>Axiron<br>Fortesta<br>Natesto<br>Striant<br>Testoderm<br>Testim<br>Testoderm TTS<br>Testopel<br>Testosterone<br>Depo-Testosterone<br>Testosterone Cypionate<br>Delatestryl<br>Testosterone Enanthate<br>Testosterone Propionate<br>Aveed<br>Depo-Testadiol<br>Testosterone Cypionate/Estradiol Cypionate<br>Ditrate-ds<br>Testosterone Enanthate/Estradiol Valerate |
|                               |                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Thioridazine HCL</b>       | Mellaril<br>Thioridazine<br>Thioridazine Intensol                                                                                                                                                                                                                                                                                                                                            |
| <b>Tolcapone</b>              | Tasmar<br>Tolcapone                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Valproate</b>              |                                                                                                                                                                                                                                                                                                                                                                                              |
| Divalproex Sodium             | Divalproex Sodium                                                                                                                                                                                                                                                                                                                                                                            |

|                    |                                                                            |
|--------------------|----------------------------------------------------------------------------|
| Valproic Acid      | Depakote<br>Depakote ER<br>Depakote Sprinkles<br>Valproic Acid<br>Depakene |
| Valproate Sodium   | Stavzor<br>Valproate Sodium<br>Depacon<br>Depakene                         |
| <b>Zafirlukast</b> | Accolate<br>Zafirlukast                                                    |
| <b>Zileuton</b>    | Zyflo<br>Zyflo CR                                                          |

\* Systemic use only.

## References

Pandit A, Sachdeva T, Bafna P. Drug-Induced Hepatotoxicity: A Review. *J Applied Pharma Science* 02 (05); 2012:233-243.

Mehta N, Ozick LA, Gbadehan E. Drug-Induced Hepatotoxicity. Medscape 2014.  
<http://emedicine.medscape.com/article/169814-overview#a1> Accessed September 20, 2015.

## APPENDIX 11. INTERSTITIAL LUNG DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Risk factors and confounders for ILD are defined by the following ICD-9-CM diagnosis/procedure codes, CPT, HCPCS codes, and/or medication name or NDCs.

### ICD-9-CM Code Descriptions

| <b>Asthma</b>     |                                                          |
|-------------------|----------------------------------------------------------|
| 493               | Asthma                                                   |
| 493.0             | Extrinsic Asthma                                         |
| 493.00            | Extrinsic Asthma Unspecified                             |
| 493.01            | Extrinsic Asthma With Status Asthmaticus                 |
| 493.02            | Extrinsic Asthma With (Acute) Exacerbation               |
| 493.1             | Intrinsic Asthma                                         |
| 493.10            | Intrinsic Asthma Unspecified                             |
| 493.11            | Intrinsic Asthma With Status Asthmaticus                 |
| 493.12            | Intrinsic Asthma With (Acute) Exacerbation               |
| 493.2             | Chronic Obstructive Asthma                               |
| 493.20            | Chronic Obstructive Asthma Unspecified                   |
| 493.21            | Chronic Obstructive Asthma With Status Asthmaticus       |
| 493.22            | Chronic Obstructive Asthma With (Acute) Exacerbation     |
| 493.8             | Other Specified Asthma                                   |
| 493.81            | Exercise-Induced Bronchospasm                            |
| 493.82            | Cough Variant Asthma                                     |
| 493.9             | Asthma Unspecified                                       |
| 493.90            | Asthma Unspecified                                       |
| 493.91            | Asthma Unspecified Type With Status Asthmaticus          |
| 493.92            | Asthma Unspecified With (Acute) Exacerbation             |
| <b>Bronchitis</b> |                                                          |
| 490               | Bronchitis Not Specified As Acute Or Chronic             |
| 491               | Chronic Bronchitis                                       |
| 491.0             | Simple Chronic Bronchitis                                |
| 491.1             | Mucopurulent Chronic Bronchitis                          |
| 491.2             | Obstructive Chronic Bronchitis                           |
| 491.20            | Obstructive Chronic Bronchitis Without Exacerbation      |
| 491.21            | Obstructive Chronic Bronchitis With (Acute) Exacerbation |
| 491.22            | Obstructive Chronic Bronchitis With Acute Bronchitis     |
| 491.8             | Other Chronic Bronchitis                                 |
| 491.9             | Unspecified Chronic Bronchitis                           |
| 494               | Bronchiectasis                                           |
| 494.0             | Bronchiectasis Without Acute Exacerbation                |
| 494.1             | Bronchiectasis With Acute Exacerbation                   |
| <b>COPD</b>       |                                                          |
| 496               | Chronic Airway Obstruction Not Elsewhere Classified      |

**Connective Tissue Disease**

|        |                                            |
|--------|--------------------------------------------|
| 136.1  | Behçet syndrome (very rare)                |
| 446.21 | Goodpasture syndrome                       |
| 710.0  | Systemic lupus erythematosus               |
| 710.1  | Systemic sclerosis                         |
| 710.2  | Sjögren syndrome                           |
| 710.3  | Dermatomyositis                            |
| 710.4  | Polymyositis                               |
| 710.8  | Mixed connective tissue disease            |
| 710.9  | Undifferentiated connective tissue disease |
| 714.xx | Rheumatoid arthritis                       |
| 720.0  | Ankylosing spondylitis (rare)              |

**Exposure to Occupational and Environmental Toxins**

|       |                                                                     |
|-------|---------------------------------------------------------------------|
| 495   | Extrinsic Allergic Alveolitis                                       |
| 495.0 | Farmers' Lung                                                       |
| 495.1 | Bagassosis                                                          |
| 495.2 | Bird-Fanciers' Lung                                                 |
| 495.3 | Suberosis                                                           |
| 495.4 | Malt Workers' Lung                                                  |
| 495.5 | Mushroom Workers' Lung                                              |
| 495.6 | Maple Bark-Strippers' Lung                                          |
| 495.7 | Ventilation Pneumonitis                                             |
| 495.8 | Other Specified Allergic Alveolitis And Pneumonitis                 |
| 495.9 | Unspecified Allergic Alveolitis And Pneumonitis                     |
| 500   | Coal Workers' Pneumoconiosis                                        |
| 501   | Asbestosis                                                          |
| 502   | Pneumoconiosis Due To Other Silica Or Silicates                     |
| 503   | Pneumoconiosis Due To Other Inorganic Dust                          |
| 504   | Pneumonopathy Due To Inhalation Of Other Dust                       |
| 505   | Pneumoconiosis Unspecified                                          |
| 506   | Respiratory Conditions Due To Chemical Fumes And Vapors             |
| 506.0 | Bronchitis And Pneumonitis Due To Fumes And Vapors                  |
| 506.1 | Acute Pulmonary Edema Due To Fumes And Vapors                       |
| 506.2 | Upper Respiratory Inflammation Due To Fumes And Vapors              |
| 506.3 | Other Acute And Subacute Resp Conditions Due To Fumes And Vapors    |
| 506.4 | Chronic Respiratory Conditions Due To Fumes And Vapors              |
| 506.9 | Unspecified Respiratory Conditions Due To Fumes And Vapors          |
| 507   | Pneumonitis Due To Solids And Liquids                               |
| 507.1 | Pneumonitis Due To Inhalation Of Oils And Essences                  |
| 507.8 | Pneumonitis Due To Other Solids And Liquids                         |
| 508   | Respiratory Conditions Due To Other And Unspecified External Agents |
| 508.0 | Acute Pulmonary Manifestations Due To Radiation                     |
| 508.1 | Chronic And Other Pulmonary Manifestations Due To Radiation         |
| 508.2 | Respiratory Conditions Due To Smoke Inhalation                      |
| 508.8 | Respiratory Conditions Due To Other Specified External Agents       |
| 508.9 | Respiratory Conditions Due To Unspecified External Agent            |

**Gastroesophageal Reflux Disease**

|        |                                 |
|--------|---------------------------------|
| 530.81 | Gastroesophageal reflux disease |
|--------|---------------------------------|

**Other Anti-arrhythmic Agents** (Therapeutic class # 240404\*)

|                                            |                             |
|--------------------------------------------|-----------------------------|
| Bretylum Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylum Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride           | Quinidine Polygalacturonate |
| Disopyramide Phosphate                     | Quinidine Sulfate           |
| Lidocaine Hydrochloride                    | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                   |                             |

\* screen for only the agents list above

**Oxygen Therapy – CPT Procedure Codes**

| <b>CPT</b> | <b>CPT Description</b>                                                                                                                                                                                                                                                                          |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4030F      | Long-term oxygen therapy prescribed (more than 15 hours per day) (COPD)                                                                                                                                                                                                                         |
| 82803      | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub>                                                                                                                                                                                    |
| 82805      | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub> (including calculated O <sub>2</sub> saturation); with O <sub>2</sub> saturation, by direct measurement, except pulse oximetry                                                     |
| 82810      | Gases, blood, O <sub>2</sub> saturation only, by direct measurement, except pulse oximetry                                                                                                                                                                                                      |
| 94010      | Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation                                                                                                                                        |
| 94014      | Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and review and interpretation by a physician/other qualified health care professional |
| 94015      | Patient-initiated spirometric recording per 30-day period of time; recording                                                                                                                                                                                                                    |
| 94016      | Patient-initiated spirometric recording per 30-day period of time; review and interpretation only by a physician or other qualified health care professional                                                                                                                                    |
| 94060      | Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator admin                                                                                                                                                                                                      |
| 94070      | Bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (eg, antigen[s], cold air, methacholine)                                                                                                                                         |
| 94150      | Vital capacity, total (separate procedure)                                                                                                                                                                                                                                                      |
| 94200      | Maximum breathing capacity, maximal voluntary ventilation                                                                                                                                                                                                                                       |
| 94250      | Expired gas collection, quantitative, single procedure (separate procedure)                                                                                                                                                                                                                     |
| 94375      | Respiratory flow volume loop                                                                                                                                                                                                                                                                    |
| 94400      | Breathing response to CO <sub>2</sub> (CO <sub>2</sub> response curve)                                                                                                                                                                                                                          |
| 94450      | Breathing response to hypoxia (hypoxia response curve)                                                                                                                                                                                                                                          |
| 94452      | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional;                                                                                                                                                                |
| 94453      | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional; with supplemental oxygen titration                                                                                                                             |

|       |                                                                                                                                          |
|-------|------------------------------------------------------------------------------------------------------------------------------------------|
| 94610 | Intrapulmonary surfactant administration by a physician or other qualified health care professional through endotracheal tube            |
| 94620 | Pulmonary stress testing; simple                                                                                                         |
| 94621 | Pulmonary stress testing; complex                                                                                                        |
| 94640 | Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes          |
| 94642 | Aerosol inhalation of pentamidine for pneumocystis carinii pneumonia treatment/prophylaxis                                               |
| 94644 | Continuous inhalation treatment w aerosol medication for acute airway obstruction; 1 <sup>st</sup> hour                                  |
| 94645 | Continuous inhalation treatment w/ aerosol medication for acute airway obstruction; ea add hr                                            |
| 94660 | Continuous positive airway pressure ventilation (CPAP), initiation and management                                                        |
| 94662 | Continuous negative pressure ventilation (CNP), initiation and management                                                                |
| 94664 | Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device           |
| 94667 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation |
| 94668 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent                              |
| 94680 | Oxygen uptake, expired gas analysis; rest and exercise, direct, simple                                                                   |
| 94681 | Oxygen uptake, expired gas analysis; including CO2 output, percentage oxygen extracted                                                   |
| 94690 | Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)                                                                 |
| 94726 | Plethysmography for determination of lung volumes and, when performed, airway resistance                                                 |
| 94727 | Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes           |
| 94728 | Airway resistance by impulse oscillometry                                                                                                |
| 94729 | Diffusing capacity (eg, carbon monoxide, membrane)                                                                                       |
| 94750 | Pulmonary compliance study (eg, plethysmography, volume and pressure measurements)                                                       |
| 94760 | Noninvasive ear or pulse oximetry for oxygen saturation; single determination                                                            |
| 94761 | Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations                                                         |
| 94762 | Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring                                              |
| 94770 | Carbon dioxide, expired gas determination by infrared analyzer                                                                           |
| 99503 | Home visit - respiratory therapy care (eg, oxygen therapy, respiratory assessment, apnea eval)                                           |
| 99504 | Home visit for mechanical ventilation care                                                                                               |

#### Oxygen Therapy – HCPCS Procedure Codes

| HCPCS | HCPCS Description                                                                                                                                           |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E0424 | Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing |
| E0425 | Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                               |



|       |                                                                                                                                                                                                                                                      |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E0430 | Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing                                                                                                                                     |
| E0431 | Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing                                                                                                                   |
| E0433 | Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and content gauge |
| E0434 | Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing                                                                             |
| E0435 | Portable liquid oxygen system purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor                                                                             |
| E0439 | Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                                      |
| E0440 | Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                   |
| E0441 | Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit                                                                                  |
| E0442 | Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit                                                                                     |
| E0443 | Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                                                                            |
| E0444 | Portable oxygen contents, liquid (for use only with portable liquid systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                                                                              |
| E1390 | Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate                                                                                                              |
| E1391 | Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each                                                                                                          |
| E1392 | Portable oxygen concentrator, rental                                                                                                                                                                                                                 |
| E1405 | Oxygen and water vapor enriching system with heated delivery                                                                                                                                                                                         |
| E1406 | Oxygen and water vapor enriching system without heated delivery                                                                                                                                                                                      |
| K0738 | Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing                                                          |
| K0741 | Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches                                                                                            |
| S8120 | Oxygen contents, gaseous, 1 unit equals 1 cubic foot                                                                                                                                                                                                 |
| S8121 | Oxygen contents, liquid, 1 unit equals 1 pound                                                                                                                                                                                                       |

## AGENTS ASSOCIATED WITH DRUG-INDUCED PULMONARY DISEASE

Generic Name (Alias)

Study Period: 7/20/2008 to 9/30/2014

Product Name

### Low Risk Categories

#### Antimicrobial Medications

|                                              |                                                                                             |
|----------------------------------------------|---------------------------------------------------------------------------------------------|
| Ethambutol HCL                               | Ethambutol HCL<br>Myambutol                                                                 |
| Isoniazid (Isonicotinic acid hydrazide; INH) | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid<br>Nydrasid<br>Rimifon<br>Stanozide  |
| Isoniazid/Rifampin                           | Rifamate<br>Isoniazid/Rifampin                                                              |
| Isoniazid/Pyrazinamide/Rifampin              | Rifater                                                                                     |
| Minocycline                                  | Minocycline HCL<br>Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                       |
| Sulfasalazine                                | Sulfasalazine<br>Azulfidine<br>Azulfidine EN-tabs<br>Sulfazine<br>Sulfazine EC<br>S.A.S.500 |

#### Cardiovascular Agents

|                                    |                                              |
|------------------------------------|----------------------------------------------|
| ACE inhibitors                     |                                              |
| Benazepril HCL                     | Benazepril HCL<br>Lotensin                   |
| Amlodipine Besylate/Benazepril HCL | Amlodipine besylate/Benazepril HCL<br>Lotrel |
| Captopril                          | Captopril<br>Capoten                         |
| Enalapril Maleate Oral             | Enalapril Maleate<br>Epaned<br>Vasotec       |
| Enalaprilat                        | Enalaprilat                                  |
| Enalapril Maleate/Felodipine       | Lexxel                                       |
| Enalapril Maleate/Diltiazem Malate | Teczem                                       |
| Fosinopril Sodium                  | Fosinopril Sodium<br>Monopril                |
| Lisinopril                         | Lisinopril<br>Prinivil<br>Zestril            |
| Moexipril HCL                      | Moexipril HCL<br>Univasc                     |
| Perindopril Erbumine               | Perindopril Erbumine<br>Aceon                |
| Quinapril HCL                      | Quinapril HCL                                |

|                               |                            |
|-------------------------------|----------------------------|
|                               | Accupril                   |
| Ramipril                      | Ramipril                   |
|                               | Altace                     |
| Trandolapril                  | Trandolapril               |
|                               | Mavik                      |
| Trandolapril/Verapamil HCL    | Tarka                      |
|                               | Trandolapril/Verapamil HCL |
| Amiodarone HCL                | Amiodarone HCL             |
|                               | Cordarone                  |
|                               | Nexterone                  |
|                               | Pacerone                   |
| <b>Anticoagulants</b>         |                            |
| Apixaban                      | Eliquis                    |
| Dabigatran Etexilate Mesylate | Pradaxa                    |
| Vorapaxar Sulfate             | Zontivity                  |
| Rivaroxaban                   | Xarelto                    |
|                               | Xarelto Starter Pack       |
| Warfarin Sodium Oral          | Warfarin Sodium            |
|                               | Athrombin                  |
|                               | Athrombin K                |
|                               | Coumadin                   |
|                               | Jantoven                   |
|                               | Panwarfin                  |
| Warfarin Potassium            | Athrombin K                |
| Ticagrelor                    | Brilinta                   |
| <b>Beta Blockers</b>          |                            |
| Acebutolol HCL                | Acebutolol HCL             |
|                               | Sectral                    |
| Atenolol                      | Atenolol                   |
|                               | Tenormin                   |
| Betaxolol HCL                 | Betaxolol HCL              |
|                               | Kerlone                    |
| Bisoprolol Fumarate           | Bisoprolol Fumarate        |
|                               | Zebeta                     |
|                               | Cartrol                    |
| Carteolol HCL                 | Cartrol                    |
| Carvedilol                    | Carvedilol                 |
|                               | Coreg                      |
| Carvedilol Phosphate          | Coreg CR                   |
| Esmolol HCL                   | Esmolol HCL                |
|                               | Brevibloc                  |
| Labetalol HCL                 | Labetalol HCL              |
|                               | Normodyne                  |
|                               | Trandate                   |
| Metoprolol                    |                            |
| Metoprolol Succinate          | Metoprolol Succinate       |
|                               | Toprol XL                  |
| Metoprolol Tartrate           | Metoprolol Tartrate        |
|                               | Lopressor                  |
| Nadolol                       | Nadolol                    |
|                               | Corgard                    |
| Nebivolol HCL                 | Nebivolol HCL              |
|                               | Bystolic                   |
| Penbutolol Sulfate            | Levatul                    |
| Pindolol                      | Pindolol                   |
|                               | Visken                     |
| Propranolol HCL               | Propranolol HCL            |

|                                                                    |                                                                                                                            |
|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
|                                                                    | Hemangeol<br>Inderal LA<br>Inderal XL<br>InnoPran XL                                                                       |
| Timolol Maleate                                                    | Timolol Maleate                                                                                                            |
| Flecainide Acetate                                                 | Flecainide Acetate<br>Tambocor                                                                                             |
| Hydralazine HCL                                                    | Hydralazine HCL<br>Dralzine<br>Apresoline                                                                                  |
| Hydralazine/Isosorbide dinitrate                                   | BiDil                                                                                                                      |
| Hydralazine/Hydrochlorothiazide/Reserpine                          | Cam-Ap-Es<br>Hydralazine/Hydrochlorothiazide/Reserpine<br>Hydrap-ES<br>Hydroserpine plus (r-h-h)<br>SER-A-GEN<br>SER-AP-ES |
| Hydralazine/Reserpine                                              | Unipres<br>Dralserp<br>Serpasil-Apresoline                                                                                 |
| Hydrochlorothiazide                                                | Esidrix<br>Hydrochlorothiazide<br>Hydro-D<br>Hydrodiuril<br>Microzide<br>Oretic<br>Zide                                    |
| Spironolactone/Hydrochlorothiazide                                 | Aldactazide<br>Spironolactone/Hydrochlorothiazide                                                                          |
| Methyldopa/Hydrochlorothiazide                                     | Aldoril<br>Methyldopa/Hydrochlorothiazide                                                                                  |
| Amiloride HCL/Hydrochlorothiazide                                  | Amiloride HCL/Hydrochlorothiazide<br>Hydro-ride<br>Moduretic                                                               |
| Amlodipine/ Valsartan/Hydrochlorothiazide                          | Amlodipine/ Valsartan/Hydrochlorothiazide                                                                                  |
| Aliskiren Hemifumarate/Hydrochlorothiazide                         | Tekturna HCT                                                                                                               |
| Aliskiren Hemifumarate/Amlodipine Besylate/<br>Hydrochlorothiazide | Amturnide                                                                                                                  |
| Candesartan Cilexetil/Hydrochlorothiazide                          | Atacand HCT<br>Candesartan Cilexetil/Hydrochlorothiazide                                                                   |
| Irbesartan/Hydrochlorothiazide                                     | Avalide<br>Irbesartan/Hydrochlorothiazide                                                                                  |
| Olmesartan Medoxomil/Hydrochlorothiazide                           | Benicar HCT                                                                                                                |
| Valsartan/Hydrochlorothiazide                                      | Diovan HCT<br>Valsartan/Hydrochlorothiazide                                                                                |
| Triamterene/Hydrochlorothiazide                                    | Dyazide<br>Maxzide<br>Triamterene/Hydrochlorothiazide                                                                      |
| Guanethidine monosulfate/Hydrochlorothiazide                       | Esimil                                                                                                                     |
| Amlodipine/Valsartan/Hydrochlorothiazide                           | Exforge HCT                                                                                                                |
| Hydrochlorothiazide/Reserpine                                      | H.R.-50<br>Hydro-Reserp<br>Hydro-serp<br>Hydropres                                                                         |
| Losartan Potassium/Hydrochlorothiazide                             | Hyzaar<br>Losartan Potassium/Hydrochlorothiazide                                                                           |
| Telmisartan/Hydrochlorothiazide                                    | Micardis HCT<br>Telmisartan/Hydrochlorothiazide                                                                            |

|                                                         |                                                                                               |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Deserpidine/Hydrochlorothiazide                         | Oreticyl<br>Oreticyl Forte                                                                    |
| Eprosartan Mesylate/Hydrochlorothiazide                 | Teveten HCT                                                                                   |
| Olmesartan Medoxomil / Amlodipine / Hydrochlorothiazide | Tribenzor                                                                                     |
| Procainamide HCL                                        | Procainamide HCL<br>Procan<br>Procan SR<br>Procanbid<br>Procapan<br>Pronestyl<br>Pronestyl-SR |
| Tocainide                                               | Tonocard                                                                                      |
| <b>ACE inhibitors/ Hydrochlorothiazide</b>              |                                                                                               |
| Benazepril HCL/Hydrochlorothiazide                      | Benazepril HCL/Hydrochlorothiazide<br>Lotensin HCT                                            |
| Captopril/Hydrochlorothiazide                           | Captopril/Hydrochlorothiazide<br>Capozide                                                     |
| Enalapril Maleate/Hydrochlorothiazide                   | Enalapril Maleate/Hydrochlorothiazide<br>Vaseretic                                            |
| Fosinopril Sodium//Hydrochlorothiazide                  | Fosinopril Sodium//Hydrochlorothiazide<br>Monopril HCT                                        |
| Lisinopril/Hydrochlorothiazide                          | Lisinopril/Hydrochlorothiazide<br>Prinzide<br>Zestoretic                                      |
| Moexipril HCL/Hydrochlorothiazide                       | Moexipril HCL/Hydrochlorothiazide<br>Uniretic                                                 |
| Quinapril HCL/Hydrochlorothiazide                       | Quinapril HCL/Hydrochlorothiazide<br>Accuretic<br>Quinaretic                                  |
| <b>Beta Blockers/Thiazide Diuretics</b>                 |                                                                                               |
| Atenolol/Chlorthalidone                                 | Atenolol/Chlorthalidone<br>Tenoretic 50                                                       |
| Betaxolol HCL/Chlorthalidone                            | Kerledex                                                                                      |
| Bisoprolol Fumarate/Hydrochlorothiazide                 | Bisoprolol Fumarate/Hydrochlorothiazide<br>Ziac                                               |
| Labetalol HCL/Hydrochlorothiazide                       | Normozide<br>Trandate HCT                                                                     |
| Metoprolol Succinate/Hydrochlorothiazide                | Dutoprol                                                                                      |
| Metoprolol Tartrate/Chlorthalidone                      | Lopressidone                                                                                  |
| Metoprolol Tartrate/Hydrochlorothiazide                 | Metoprolol Tartrate/Hydrochlorothiazide<br>Lopressor HCT                                      |
| Nadolol/Bendroflumethiazide                             | Nadolol/Bendroflumethiazide<br>Corzide                                                        |
| Pindolol/Hydrochlorothiazide                            | Viskazine                                                                                     |
| Propranolol HCL/Hydrochlorothiazide                     | Propranolol HCL/Hydrochlorothiazide<br>Inderide<br>Inderide LA                                |
| Timolol Maleate/Hydrochlorothiazide                     | Timolide 10-25                                                                                |
| Hydralazine/Hydrochlorothiazide                         | Hydra-Zide<br>Apresoline-Esidrix                                                              |
| <b>Miscellaneous</b>                                    |                                                                                               |
| Phentermine HCL                                         | Adipex-P<br>Fastin<br>Obestin-30<br>Oby-Trim<br>Ona-Mast                                      |

Phentermine HCL  
Suprenza  
Tora  
Wilpo

## High Risk Categories

### Anti-Inflammatory Medications

|                                  |                      |
|----------------------------------|----------------------|
| Gold                             |                      |
| Gold Sodium Thiomalate           | Myochrysine          |
| Auranofin (29% Gold)             | Ridaura              |
| Methotrexate (Amethopterin; MTX) | Methotrexate         |
|                                  | Abitrexate           |
|                                  | Folex PFS            |
|                                  | Mexate-AQ Preserved  |
|                                  | Mexate               |
|                                  | Rheumatrex Dose Pack |
|                                  | Otrexup              |
|                                  | Rasuvo               |
|                                  | Trexall              |
| Penicillamine                    | Cuprimine            |
|                                  | Depen Titratabs      |

### Monoclonal Antibodies- Antineoplastics

|             |           |
|-------------|-----------|
| Alemtuzumab | Campath   |
|             | Lemtrada  |
| Bevacizumab | Avastin   |
| Cetuximab   | Erbitux   |
| Rituximab   | Rituxan   |
| Trastuzumab | Herceptin |

### Tumor Necrosis Factor-alpha (TNFα) blockers

|                                     |                                |
|-------------------------------------|--------------------------------|
| Adalimumab                          | Humira                         |
| Certolizumab Pegol                  | Cimzia (Prefilled/Starter Kit) |
| Etanercept                          | Enbrel                         |
| Golimumab                           | Simponi                        |
|                                     | Simponi Aria                   |
| Infliximab                          | Remicade                       |
| Immune Globulin Intravenous (Human) | Bivigam                        |
|                                     | Carimune NF                    |
|                                     | Flebogamma DIF                 |
|                                     | Gammagard S/D                  |
|                                     | Gammagard S/D Less IgA         |
|                                     | Gammaplex                      |
|                                     | Octagam                        |

### Chemotherapeutic Agents

|                            |                   |
|----------------------------|-------------------|
| Bicalutamide               | Bicalutamide      |
|                            | Casodex           |
| Bleomycin Sulfate          | Bleomycin Sulfate |
|                            | Blenoxane         |
| Busulfan                   | Busulfex          |
|                            | Myleran           |
| Carboplatin                | Carboplatin       |
| Capecitabine               | Capecitabine      |
|                            | Xeloda            |
| Carmustine (BCNU)          | BiCNU             |
| Carmustine in Polifeprosan | Gliadel Wafer     |
| Chlorambucil               | Leukeran          |
| Cisplatin (CDDP)           | Cisplatin         |

|                                       |                                                                                       |
|---------------------------------------|---------------------------------------------------------------------------------------|
|                                       | Platinol                                                                              |
| Cyclophosphamide                      | Cyclophosphamide<br>Cytosan<br>Neosar                                                 |
| Cytarabine                            | Cytarabine<br>Cytosar-U<br>DepoCyt                                                    |
| Cytarabine Liposome                   |                                                                                       |
| Doxorubicin HCL                       | Adriamycin PFS<br>Doxil (Liposomal)<br>Doxorubicin HCL<br>Doxorubicin HCL (liposomal) |
| Erlotinib                             | Erlotinib HCL<br>Tarceva                                                              |
| Etoposide                             | Etoposide<br>Toposar<br>VePesid<br>Etopophos                                          |
| Etoposide Phosphate                   |                                                                                       |
| Floxuridine                           | Floxuridine<br>FUDR                                                                   |
| Fludarabine Phosphate                 | Fludara<br>Fludarabine Phosphate<br>Oforta                                            |
| Fluorouracil                          | Adrucil<br>Fluorouracil                                                               |
| Flutamide                             | Flutamide<br>Eulexin                                                                  |
| Imatinib Mesylate                     | Gleevec                                                                               |
| Interleukin 2                         |                                                                                       |
| Aldesleukin                           | Proleukin                                                                             |
| Denileukin diftitox                   | Ontak                                                                                 |
| Lomustine (CCNU)                      | Lomustine<br>Gleostine                                                                |
| Melphalan HCL (Phenylalanine mustard) | Melphalan HCL<br>Alkeran                                                              |
| Mercaptopurine                        | Mercaptopurine<br>Purinethol<br>Purixan                                               |
| Semustin                              | Methyl-CCNU                                                                           |
| Mitomycin (Mitomycin-C; MTC)          | Mitomycin<br>Mitozytrex<br>Mutamycin                                                  |
| Paclitaxel                            | Abraxane<br>Paclitaxel<br>Taxol                                                       |
| Procarbazine                          | Matulane                                                                              |
| Vinblastine Sulfate (VLB)             | Vinblastine Sulfate                                                                   |
| <b>Interferon Therapy</b>             |                                                                                       |
| Interferon Alfa -2B                   | Intron A                                                                              |
| Interferon Alfa- N3                   | Alferon N                                                                             |
| Interferon Alfacon-1                  | Infergen                                                                              |
| Interferon Beta-1A                    | Avonex<br>Rebif                                                                       |
| Interferon Beta-1B                    | Betaseron<br>Extavia                                                                  |
| Interferon Gamma-1B                   | Actimmune                                                                             |
| Peginterferon Alfa-2A                 | Pegasys                                                                               |
| Peginterferon Alfa-2B                 | PegIntron                                                                             |

|                                            |                                  |
|--------------------------------------------|----------------------------------|
| Peginterferon Beta-1A                      | Sylatron                         |
| Peginterferon alfa-2b/Ribavirin            | Plegridy                         |
|                                            | PegIntron and Rebetol Combo Pack |
| <b>Miscellaneous</b>                       |                                  |
| Amphotericin B                             | Amphotericin B                   |
| Amphotericin B Lipid                       | Abelcet                          |
| Amphotericin B Liposome                    | AmBisome                         |
| Amphotericin B Cholesteryl Sulfate Complex | Amphotec                         |
| Amphotericin B                             | Fungizone                        |
| Azathioprine                               | Azathioprine                     |
|                                            | Azasan                           |
|                                            | Imuran                           |
| Nitrofurantoin                             | Nitrofurantoin                   |
| Nitrofurantoin                             | Furadantin                       |
|                                            | Furalan                          |
| Nitrofurantoin Sodium                      | Ivadantin                        |
| Nitrofurantoin macrocrystalline            | Nitrofurantoin Macrocrystal      |
|                                            | Macrodantin                      |
| Nitrofurantoin monohydrate/macrocrystals   | Nitrofurantoin Monohyd Macro     |
|                                            | Macrobid                         |

\* Systemic use only.

## References

- Matsuno O. Drug induced interstitial lung disease: mechanisms and best diagnostic approaches. *Respir Res.* 2012;13:39.
- Schwaiblmair M, Behr W, Haeckel T, Markl B, Foerg W, Berghaus T. Drug-Induced Interstitial Lung Disease. *The Open Respiratory Medicine Journal.* 2012;6:63-74.
- Fernandez AB, KarasRH, Alsheikh-AliAA, ThompsonPD. Statins and Interstitial Lung Disease. *CHEST* 2008; 134:824-830.
- CamusP, FantonA, BonniaudP, Camus C FoucherP. Interstitial Lung Disease Induced by Drugs and Radiation. *Respiration* 2004;71:301-326.



## APPENDIX 12: PROPENSITY SCORE GENERATION AND MATCHING

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## A. INTRODUCTION

*NOTE: The following abbreviations are used throughout this appendix: MQ = dronedarone; AM=amiodarone; SO=sotalol; FL=flecainide.*

Because patients in this study were not randomly assigned to cohorts, confounders cannot be assumed to be balanced across cohorts in the entire DoD database. Propensity Score (PS) matching was performed to select subsets of subjects from the database for the two primary analysis datasets (SLD and ILD Narrow definition) and for the ILD Broad definition analysis dataset, in order to achieve closer matching of baseline variables between the cohorts.

The process of generating propensity scores and matching patients by PS was conducted separately for each analysis group. Different logistic regression models were used to generate propensity scores for the two analyses as potential baseline confounders varied between the SLD and ILD outcomes.

The PS matching process was also conducted separately for the SLD analysis, ILD Narrow definition analysis and ILD Broad definition analysis. Analysis datasets consisted of MQ subject records and their matching comparator subjects (one PS-matched patient from each comparator cohort). The process, described below, used to generate propensity scores and match comparators to MQ subjects was the same for the three analysis datasets.

The goal of the PS matching was to retain as many cases as possible in the analysis datasets, while at the same time optimizing the balance of baseline confounders across the cohorts. Those two goals could not be optimized simultaneously, so a trade-off was sought. Several logistic regression models and PS matching schema were evaluated to identify one that optimized the number of cases retained for the analysis with the best balance of baseline confounders across the cohorts. Variations in independent variables (e.g., transformations of some confounder variables) and different caliper width requirements for PS matching were considered. For each variation of logistic regression model and caliper width, a table of standardized differences was generated to compare the balance of baseline confounders before and after PS matching, for the particular combination. The project statistician assessed results of the PS model – caliper width combinations and identified the optimum combination to use for the analyses.

This appendix describes the process employed to generate propensity scores and conduct the PS-matching. Also presented are results of validation tests performed on the PS-matched subsets with respect to baseline variables (comparing the balance of baseline variables between dronedarone and comparator cohorts in the full database and the PS-matched subsets) and the primary endpoints (examining the variation of hazard ratios for SLD events and ILD events across PS-based strata for each comparator cohort, relative to dronedarone).

## B. PROPENSITY SCORE GENERATION

### Stepwise Regression to Define the Reduced Propensity Score Model

Potential baseline confounders relevant to each outcome of interest (i.e., SLD and ILD) were identified in the study protocol (see [Appendix 14](#)).

Variables representing all the identified confounder variables were entered as covariates in a full logistic regression model, with membership in the MQ cohort as the dependent variable. [Table 1 – Table 3](#) list variables included in the full logistic regression models for the SLD, ILD Narrow definition, and ILD Broad definition propensity score models, respectively. The full models were run one time against the combined group of all four cohorts in each study population with enough patients to meet the requirements for the statistical power of the study (i.e., MQ, AM, SO and FL).

Stepwise logistic regression was used to identify a subset of confounder variables for inclusion in the reduced logistic regression model, from which propensity scores were generated. Variables in steps up to and including the one with the lowest Akaike Information Criterion (AIC) value were included in the reduced model. [Table 4 – Table 6](#) list the variables retained, respectively, in the SLD, ILD Narrow definition and ILD Broad definition reduced propensity score models.

**Table 1. Variables Included in the Full SLD Propensity Score Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_ALC     | Record of alcoholism in baseline (1=yes; 0=no)                                             |
| prior_BDD     | Record of bile duct disorder in baseline (1=yes; 0=no)                                     |
| prior_CHF     | Record of congestive heart failure in baseline (1=yes; 0=no)                               |
| prior_DB      | Record of diabetes in baseline (1=yes; 0=no)                                               |
| prior_OBS     | Record of obesity in baseline (1=yes; 0=no)                                                |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_AAther  | Other anti-arrhythmic therapy dispensed in baseline (1=yes; 0=no)                          |
| prior_Htox    | Potentially hepatotoxic drug dispensed in baseline (1=yes; 0=no)                           |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpli       | Number of office visits in baseline - grouped by quartile                                  |
| prior_ER      | Record of any emergency room visit in baseline (1=yes; 0=no)                               |
| rxgrpli       | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |
| prior_GE      | Record of any gastroenterologist visit in baseline (1=yes; 0=no)                           |

**Table 2. Variables Included in the Full ILD Narrow Definition Propensity Score Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_ASM     | Record of asthma in baseline (1=yes; 0=no)                                                 |
| prior_BR      | Record of bronchitis (excluding acute bronchitis) in baseline (1=yes; 0=no)                |
| prior_COP     | Record of chronic obstructive pulmonary disease in baseline (1=yes; 0=no)                  |
| prior_CTD     | Record of connective tissue disease in baseline (1=yes; 0=no)                              |
| prior_EXP     | Record of any toxin exposure in baseline (1=yes; 0=no)                                     |
| prior_RFX     | Record of gastroesophageal reflux disease in baseline (1=yes; 0=no)                        |
| prior_TOT     | Record of any therapeutic oxygen treatment in baseline (1=yes; 0=no)                       |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_AAther  | Other anti arrhythmic therapy dispensed in baseline (1=yes; 0=no)                          |
| prior_Itox    | Potentially ILD inducing drug dispensed in baseline (1=yes; 0=no)                          |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpLDN      | Number of office visits in baseline - grouped by quartile                                  |
| prior_ER      | Record of any emergency room visit in baseline (1=yes; 0=no)                               |
| rxgrpLDN      | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |
| prior_PU      | Record of any pulmonologist visit in baseline (1=yes; 0=no)                                |

**Table 3. Variables Included in the Full ILD Broad Definition Propensity Score Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_ASM     | Record of asthma in baseline (1=yes; 0=no)                                                 |
| prior_BR      | Record of bronchitis (excluding acute bronchitis) in baseline (1=yes; 0=no)                |
| prior_COP     | Record of chronic obstructive pulmonary disease in baseline (1=yes; 0=no)                  |
| prior_CTD     | Record of connective tissue disease in baseline (1=yes; 0=no)                              |
| prior_EXP     | Record of any toxin exposure in baseline (1=yes; 0=no)                                     |
| prior_RFX     | Record of gastroesophageal reflux disease in baseline (1=yes; 0=no)                        |
| prior_TOT     | Record of any therapeutic oxygen treatment in baseline (1=yes; 0=no)                       |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_AAther  | Other anti arrhythmic therapy dispensed in baseline (1=yes; 0=no)                          |
| prior_Itox    | Potentially ILD inducing drug dispensed in baseline (1=yes; 0=no)                          |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpLDB      | Number of office visits in baseline - grouped by quartile                                  |
| prior_ER      | Record of any emergency room visit in baseline (1=yes; 0=no)                               |
| rxgrpLDB      | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |
| prior_PU      | Record of any pulmonologist visit in baseline (1=yes; 0=no)                                |

**Table 4. Variables Included in the SLD Reduced Propensity Score Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_BDD     | Record of bile duct disorder in baseline (1=yes; 0=no)                                     |
| prior_CHF     | Record of congestive heart failure in baseline (1=yes; 0=no)                               |
| prior_DB      | Record of diabetes in baseline (1=yes; 0=no)                                               |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_Htox    | Potentially hepatotoxic drug dispensed in baseline (1=yes; 0=no)                           |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpli       | Number of office visits in baseline - grouped by quartile                                  |
| prior_ER      | Record of any emergency room visit in baseline (1=yes; 0=no)                               |
| rxgrpli       | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |
| prior_GE      | Record of any gastroenterologist visit in baseline (1=yes; 0=no)                           |

**Table 5. Variables Included in the ILD Narrow Definition Reduced Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_ASM     | Record of asthma in baseline (1=yes; 0=no)                                                 |
| prior_RFX     | Record of gastroesophageal reflux disease in baseline (1=yes; 0=no)                        |
| prior_TOT     | Record of any therapeutic oxygen treatment in baseline (1=yes; 0=no)                       |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_Itox    | Potentially ILD inducing drug dispensed in baseline (1=yes; 0=no)                          |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpLDN      | Number of office visits in baseline - grouped by quartile                                  |
| prior_ER      | Record of any emergency room visit in baseline (1=yes; 0=no)                               |
| rxgrpLDN      | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |
| prior_PU      | Record of any pulmonologist visit in baseline (1=yes; 0=no)                                |

**Table 6. Variables Included in the ILD Broad Definition Reduced Model**

| Variable name | Description                                                                                |
|---------------|--------------------------------------------------------------------------------------------|
| Age           | Age as a continuous variable                                                               |
| sex           | Gender (1=male,0=female)                                                                   |
| studyyr       | 12-month period from 7/1/2009 where index date falls (1,2,3,4 or 5)                        |
| prior_ASM     | Record of asthma in baseline (1=yes; 0=no)                                                 |
| prior_RFX     | Record of gastroesophageal reflux disease in baseline (1=yes; 0=no)                        |
| prior_TOT     | Record of any therapeutic oxygen treatment in baseline (1=yes; 0=no)                       |
| prior_StudyRx | One or more study drugs dispensed in baseline (1=yes; 0=no)                                |
| prior_Itox    | Potentially ILD inducing drug dispensed in baseline (1=yes; 0=no)                          |
| prior_hosp    | Record of any hospitalization in baseline (1=yes; 0=no)                                    |
| OVgrpLDB      | Number of office visits in baseline - grouped by quartile                                  |
| rxgrpLDB      | Number of different drugs dispensed in baseline by therapeutic class – grouped by quartile |



## **C. GENERATE PROPENSITY SCORES FROM REDUCED LOGISTIC REGRESSION MODEL**

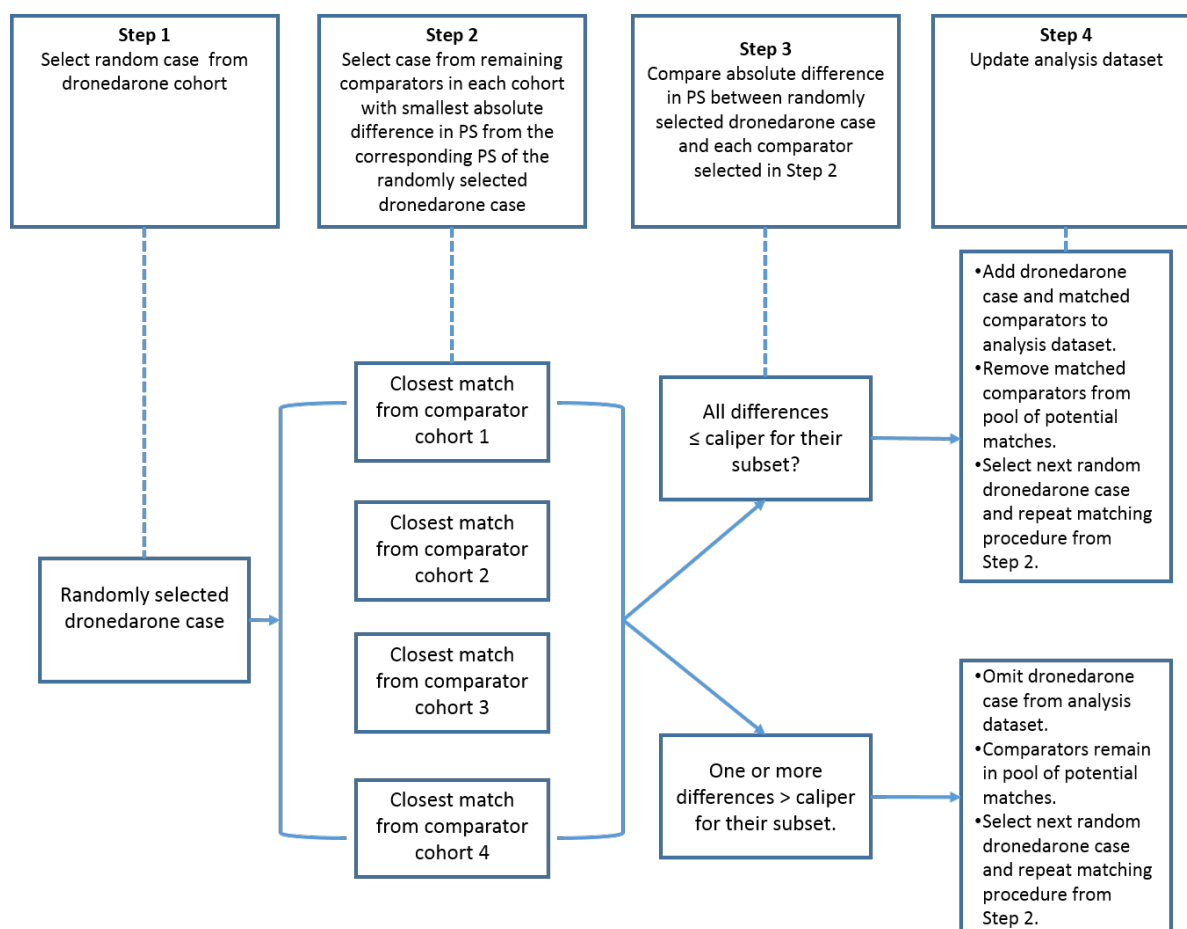
The reduced logistic model was fitted separately to a subset of the relevant study population containing only the MQ cohort and one of the comparator cohorts. The log-odds of the probability predicted by the reduced logistic regression model for each patient was used as the PS. (The log-odds is the linear portion of the value predicted by the logistic model, prior to transformation into a probability.) A PS was calculated for patients in each subset from the version of the regression model as fitted to patients in the subset (i.e., all dronedarone patients plus one set of comparator subjects at a time). Each dronedarone patient therefore had a distinct PS for matching to each comparator cohort.

## **D. PROPENSITY SCORE MATCHING**

Each of the three comparator cohorts (AM, SO, and FL) were matched independently to the MQ cohort, using their relevant propensity scores. A nearest-neighbor-within-caliper matching algorithm was employed. The initial caliper width was set at 0.2 times the standard deviation of the PS for the subset being matched. Alternate caliper widths were tested for evaluation of the trade-off between sample size and covariate balance. The alternate calipers were 0.1 and 0.05 times the standard deviation of the PS for the subset being matched. In addition, a nearest neighbor match, without a caliper requirement, was also tested. Evaluation of the PS-matched datasets, as described below, resulted in selection of the datasets generated using the 0.2 caliper for outcomes analyses. Specific calculations employed in the PS matching are detailed in the study Statistical Analysis Plan (SAP) (see [Appendix 15](#)). **Figure 1** provides a graphical representation of the matching process.

For each matching scheme tested, the MQ patients were first shuffled into random order. One MQ patient at a time was selected from the randomly ordered list. For each randomly selected patient in the MQ cohort, the “distance” to every available patient in the comparator cohort was calculated (i.e., the absolute difference in centered PS score between MQ and comparator patient), and the closest comparator patient was selected for matching. Once a comparator was selected for matching, it was no longer available for subsequent matching to other MQ patients (i.e., there was no “re-use” of comparators). If a subject within the established “caliper” distance could not be found in every comparator group, the MQ subject was considered unmatchable and omitted from the analysis dataset.

**Figure 1. Propensity Score Matching Process**



## **E. VALIDATE PROPENSITY SCORE BALANCE ON BASELINE VARIABLES**

Between-cohort balance in baseline variables (possible confounders) was evaluated in terms of the standardized difference (“Z-scores”) for each comparator cohort, relative to the MQ cohort. Standardized difference calculations are described in detail in the study SAP (see [Appendix 15](#)). In this study, baseline confounders were considered well balanced if the standardized difference was 10% or less. Confounders with standardized differences >25% after PS matching were considered severely unbalanced. Any confounders assessed as severely unbalanced after PS matching were included as explicit covariates in the Cox proportional hazards regression models used for the survival analyses.

### **SLD**

[Table 7](#) through [Table 10](#) summarize the standardized differences between the MQ and comparator cohorts for the SLD study population and its corresponding PS-matched subsets under the four matching schemes tested.

**Table 7. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Population vs. SLD Analysis Dataset Before and After Propensity Score Matching: DoD Database - 20 July 2009 to 30 September 2014 (Caliper=.2; 4,123 matches per cohort)**

|                                              | Prior to PS Matching |           |           |           |                       |           |           | PS-Matched Subsets |           |           |           |                       |           |           |
|----------------------------------------------|----------------------|-----------|-----------|-----------|-----------------------|-----------|-----------|--------------------|-----------|-----------|-----------|-----------------------|-----------|-----------|
|                                              | Mean Value or %      |           |           |           | 100*Difference/<br>SD |           |           | Mean Value or %    |           |           |           | 100*Difference/<br>SD |           |           |
| <b>Covariates</b>                            | <b>MQ</b>            | <b>AM</b> | <b>SO</b> | <b>FL</b> | <b>AM</b>             | <b>SO</b> | <b>FL</b> | <b>MQ</b>          | <b>AM</b> | <b>SO</b> | <b>FL</b> | <b>AM</b>             | <b>SO</b> | <b>FL</b> |
| Gender (% female)                            | 46.9%                | 41.5%     | 47.0%     | 50.2%     | 10.8                  | 0.3       | 6.7       | 50.5%              | 49.6%     | 47.9%     | 50.5%     | 1.8                   | 5.3       | 0.0       |
| Age on index date (mean)                     | 70.4                 | 73.8      | 71.2      | 64.2      | 36.4                  | 7.7       | 53.6      | 67.8               | 70.5      | 70.5      | 67.3      | 25.9                  | 26.0      | 4.7       |
| Study year of index date (mean)              | 2.5                  | 2.9       | 2.8       | 3.0       | 27.9                  | 21.2      | 33.7      | 2.9                | 2.5       | 2.6       | 2.8       | 31.2                  | 22.3      | 5.9       |
| Alcoholism-Y/N                               | 0.09%                | 0.06%     | 0.07%     | 0.12%     | 0.9                   | 0.6       | 0.9       | 0.07%              | 0.05%     | 0.07%     | 0.12%     | 1.0                   | 0.0       | 1.6       |
| Bile duct disorders-Y/N                      | 2.6%                 | 4.9%      | 3.0%      | 2.1%      | 11.5                  | 2.6       | 3.3       | 2.3%               | 2.2%      | 2.8%      | 2.2%      | 0.7                   | 3.1       | 0.3       |
| Congestive Heart Failure-Y/N                 | 25.4%                | 52.1%     | 30.2%     | 11.6%     | 55.4                  | 10.8      | 34.8      | 14.1%              | 19.8%     | 25.6%     | 13.9%     | 15                    | 28.9      | 0.6       |
| Diabetes-Y/N                                 | 32.6%                | 41.4%     | 34.0%     | 19.9%     | 18.2                  | 3.0       | 28.4      | 23.6%              | 30.7%     | 32.4%     | 22.9%     | 16                    | 19.7      | 1.5       |
| Obesity-Y/N                                  | 15.5%                | 17.3%     | 16.3%     | 16.1%     | 4.8                   | 2.1       | 1.6       | 15.5%              | 15.4%     | 15.3%     | 15.8%     | 0.2                   | 0.5       | 0.8       |
| Use of other study medications-Y/N           | 3.1%                 | 0.5%      | 1.0%      | 0.8%      | 23.9                  | 14.5      | 15.3      | 1.0%               | 2.3%      | 1.5%      | 0.9%      | 10.2                  | 5.0       | 0.2       |
| Prescription for other anti-arrhythmics-Y/N  | 0.5%                 | 0.5%      | 0.4%      | 0.4%      | 0.6                   | 2.6       | 2.2       | 0.4%               | 0.4%      | 0.4%      | 0.4%      | 0.8                   | 0.0       | 0.0       |
| Prescription for hepatotoxic medications-Y/N | 62.8%                | 69.7%     | 63.5%     | 56.5%     | 14.8                  | 1.4       | 13        | 58.9%              | 61.0%     | 62.0%     | 58.1%     | 4.3                   | 6.4       | 1.6       |
| Hospitalized-Y/N                             | 52.7%                | 78.9%     | 67.4%     | 40.6%     | 60.1                  | 30.4      | 24.3      | 45.6%              | 46.8%     | 56.0%     | 43.1%     | 2.3                   | 20.9      | 5.1       |
| Number of office visits (mean)               | 12.9                 | 12.1      | 11.9      | 11.4      | 8.4                   | 10.8      | 16.2      | 11.5               | 12.7      | 12.5      | 11.9      | 12.9                  | 11.2      | 4.3       |
| Visited ER-Y/N                               | 56.7%                | 62.2%     | 60.5%     | 56.2%     | 11.1                  | 7.6       | 1.2       | 54.9%              | 55.4%     | 57.7%     | 54.6%     | 1.0                   | 5.5       | 0.7       |
| Number of different medications (mean)       | 11.8                 | 12.9      | 11.5      | 9.5       | 19.3                  | 3.6       | 38.6      | 10.3               | 11.5      | 11.5      | 10.1      | 21.6                  | 21.2      | 3.1       |
| Gastroenterology specialty visits-Y/N        | 15.6%                | 15.7%     | 14.5%     | 12.8%     | 0.3                   | 2.9       | 8.0       | 13.4%              | 14.6%     | 15.1%     | 13.9%     | 3.7                   | 5.1       | 1.6       |

Abbreviations: PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 8. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Study Population vs. SLD Analysis Dataset according to Study Drug Cohort: DOD Database - July 20, 2009 to September 30, 2014 (Caliper=.1; 4,094 matches per cohort)**

|                                             | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|---------------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                             | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                                  | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                           | 46.9%                | 41.5% | 47.0% | 50.2% | 10.8              | 0.3  | 6.7  | 50.5%              | 49.4% | 47.9% | 50.6% | 2.3               | 5.3  | 0.1 |
| Age on index date (mean)                    | 70.4                 | 73.8  | 71.2  | 64.2  | 36.4              | 7.7  | 53.6 | 67.8               | 70.5  | 70.5  | 67.4  | 25.8              | 26   | 4.6 |
| Study year of index date (mean)             | 2.5                  | 2.9   | 2.8   | 3.0   | 27.9              | 21.2 | 33.7 | 2.9                | 2.5   | 2.6   | 2.8   | 32.5              | 22.8 | 7.2 |
| Alcoholism-Y/N                              | 0.1%                 | 0.1%  | 0.1%  | 0.1%  | 0.9               | 0.6  | 0.9  | 0.1%               | 0.0%  | 0.1%  | 0.1%  | 1.0               | 0.0  | 1.6 |
| Bile duct disorders-Y/N                     | 2.6%                 | 4.9%  | 3.0%  | 2.1%  | 11.5              | 2.6  | 3.3  | 2.3%               | 2.2%  | 2.8%  | 2.2%  | 0.5               | 3.3  | 0.5 |
| Congestive Heart Failure-Y/N                | 25.4%                | 52.1% | 30.2% | 11.6% | 55.4              | 10.8 | 34.8 | 14.3%              | 20.0% | 25.7% | 14.0% | 15.3              | 28.9 | 0.8 |
| Diabetes-Y/N                                | 32.6%                | 41.4% | 34.0% | 19.9% | 18.2              | 3.0  | 28.4 | 23.5%              | 30.7% | 32.5% | 23.0% | 16.3              | 20.1 | 1.2 |
| Obesity-Y/N                                 | 15.5%                | 17.3% | 16.3% | 16.1% | 4.8               | 2.1  | 1.6  | 15.7%              | 15.5% | 15.6% | 15.8% | 0.7               | 0.4  | 0.2 |
| Use of other study medications-Y/N          | 3.1%                 | 0.5%  | 1.0%  | 0.8%  | 23.9              | 14.5 | 15.3 | 0.9%               | 2.2%  | 1.5%  | 1.0%  | 10.8              | 5.6  | 0.5 |
| Prescription for other anti-arrhythmics-Y/N | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.6               | 2.6  | 2.2  | 0.4%               | 0.4%  | 0.4%  | 0.4%  | 0.8               | 0.0  | 0.0 |
| Potentially hepatotoxic medication-Y/N      | 62.8%                | 69.7% | 63.5% | 56.5% | 14.8              | 1.4  | 13.0 | 58.9%              | 61.1% | 62.0% | 58.1% | 4.5               | 6.3  | 1.7 |
| Hospitalized-Y/N                            | 52.7%                | 78.9% | 67.4% | 40.6% | 60.1              | 30.4 | 24.3 | 45.7%              | 47.1% | 56.2% | 43.2% | 2.6               | 21.0 | 5.1 |
| Number of office visits (mean)              | 12.9                 | 12.1  | 11.9  | 11.4  | 8.4               | 10.8 | 16.2 | 11.5               | 12.7  | 12.5  | 11.9  | 13.2              | 10.9 | 4.2 |
| Visited ER-Y/N                              | 56.7%                | 62.2% | 60.5% | 56.2% | 11.1              | 7.6  | 1.2  | 55.1%              | 55.4% | 57.7% | 54.5% | 0.6               | 5.2  | 1.2 |
| Number of different medications (mean)      | 11.8                 | 12.9  | 11.5  | 9.5   | 19.3              | 3.6  | 38.6 | 10.3               | 11.5  | 11.5  | 10.1  | 21.3              | 21.0 | 3.4 |
| Gastroenterology specialty visits-Y/N       | 15.6%                | 15.7% | 14.5% | 12.8% | 0.3               | 2.9  | 8.0  | 13.4%              | 14.8% | 15.0% | 13.9% | 4.0               | 4.6  | 1.4 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 9. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Study Population vs. SLD Analysis Dataset according to Study Drug Cohort: DOD Database - July 20, 2009 to September 30, 2014 (Caliper=.05; 4,096 matches per cohort)**

|                                             | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|---------------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                             | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                                  | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                           | 46.9%                | 41.5% | 47.0% | 50.2% | 10.8              | 0.3  | 6.7  | 50.6%              | 49.4% | 47.9% | 50.5% | 2.5               | 5.4  | 0.3 |
| Age on index date (mean)                    | 70.4                 | 73.8  | 71.2  | 64.2  | 36.4              | 7.7  | 53.6 | 67.8               | 70.5  | 70.5  | 67.3  | 26.2              | 26.1 | 4.5 |
| Study year of index date (mean)             | 2.5                  | 2.9   | 2.8   | 3.0   | 27.9              | 21.2 | 33.7 | 2.9                | 2.5   | 2.6   | 2.8   | 32.6              | 22.2 | 7.2 |
| Alcoholism-Y/N                              | 0.1%                 | 0.1%  | 0.1%  | 0.1%  | 0.9               | 0.6  | 0.9  | 0.1%               | 0.0%  | 0.1%  | 0.1%  | 1.0               | 0.0  | 1.6 |
| Bile duct disorders-Y/N                     | 2.6%                 | 4.9%  | 3.0%  | 2.1%  | 11.5              | 2.6  | 3.3  | 2.4%               | 2.2%  | 2.9%  | 2.2%  | 1.1               | 3.5  | 1.1 |
| Congestive Heart Failure-Y/N                | 25.4%                | 52.1% | 30.2% | 11.6% | 55.4              | 10.8 | 34.8 | 14.2%              | 20.0% | 25.9% | 13.9% | 15.4              | 29.5 | 0.9 |
| Diabetes-Y/N                                | 32.6%                | 41.4% | 34.0% | 19.9% | 18.2              | 3.0  | 28.4 | 23.4%              | 30.5% | 32.6% | 22.9% | 16.0              | 20.5 | 1.2 |
| Obesity-Y/N                                 | 15.5%                | 17.3% | 16.3% | 16.1% | 4.8               | 2.1  | 1.6  | 15.8%              | 15.5% | 15.5% | 15.7% | 0.8               | 0.8  | 0.4 |
| Use of other study medications-Y/N          | 3.1%                 | 0.5%  | 1.0%  | 0.8%  | 23.9              | 14.5 | 15.3 | 0.8%               | 2.2%  | 1.4%  | 1.0%  | 11.5              | 5.4  | 1.3 |
| Prescription for other anti-arrhythmics-Y/N | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.6               | 2.6  | 2.2  | 0.4%               | 0.4%  | 0.4%  | 0.4%  | 0.8               | 0.0  | 0.0 |
| Potentially hepatotoxic medication-Y/N      | 62.8%                | 69.7% | 63.5% | 56.5% | 14.8              | 1.4  | 13.0 | 59.0%              | 61.1% | 62.0% | 58.0% | 4.4               | 6.2  | 2.0 |
| Hospitalized-Y/N                            | 52.7%                | 78.9% | 67.4% | 40.6% | 60.1              | 30.4 | 24.3 | 46.2%              | 47.3% | 56.3% | 43.2% | 2.1               | 20.3 | 6.2 |
| Number of office visits (mean)              | 12.9                 | 12.1  | 11.9  | 11.4  | 8.4               | 10.8 | 16.2 | 11.6               | 12.7  | 12.5  | 11.9  | 12.9              | 10.4 | 3.9 |
| Visited ER-Y/N                              | 56.7%                | 62.2% | 60.5% | 56.2% | 11.1              | 7.6  | 1.2  | 55.3%              | 55.5% | 58.0% | 54.6% | 0.4               | 5.4  | 1.5 |
| Number of different medications (mean)      | 11.8                 | 12.9  | 11.5  | 9.5   | 19.3              | 3.6  | 38.6 | 10.3               | 11.5  | 11.5  | 10.1  | 21.5              | 21.3 | 3.4 |
| Gastroenterology specialty visits-Y/N       | 15.6%                | 15.7% | 14.5% | 12.8% | 0.3               | 2.9  | 8.0  | 13.3%              | 14.7% | 15.0% | 13.8% | 4.1               | 4.9  | 1.4 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 10. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Study Population vs. SLD Analysis Dataset according to Study Drug Cohort: DOD Database - July 20, 2009 to September 30, 2014 (Caliper=Nearest Neighbor; 5,015 matches per cohort)**

|                                             | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |      |
|---------------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|------|
|                                             | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |      |
| Covariates                                  | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL   |
| Gender (% female)                           | 46.9%                | 41.5% | 47.0% | 50.2% | 10.8              | 0.3  | 6.7  | 46.7%              | 48.5% | 47.8% | 50.2% | 3.5               | 2.0  | 6.9  |
| Age on index date (mean)                    | 70.4                 | 73.8  | 71.2  | 64.2  | 36.4              | 7.7  | 53.6 | 70.4               | 71.3  | 70.7  | 64.2  | 8.7               | 2.1  | 52.2 |
| Study year of index date (mean)             | 2.5                  | 2.9   | 2.8   | 3.0   | 27.9              | 21.2 | 33.7 | 2.5                | 2.5   | 2.6   | 3.0   | 1.9               | 7.0  | 33.9 |
| Alcoholism-Y/N                              | 0.1%                 | 0.1%  | 0.1%  | 0.1%  | 0.9               | 0.6  | 0.9  | 0.1%               | 0.0%  | 0.1%  | 0.1%  | 2.8               | 2.0  | 0.0  |
| Bile duct disorders-Y/N                     | 2.6%                 | 4.9%  | 3.0%  | 2.1%  | 11.5              | 2.6  | 3.3  | 2.7%               | 2.5%  | 2.6%  | 2.1%  | 1.0               | 0.1  | 3.8  |
| Congestive Heart Failure-Y/N                | 25.4%                | 52.1% | 30.2% | 11.6% | 55.4              | 10.8 | 34.8 | 25.3%              | 26.0% | 26.7% | 11.6% | 1.6               | 3.1  | 35.9 |
| Diabetes-Y/N                                | 32.6%                | 41.4% | 34.0% | 19.9% | 18.2              | 3.0  | 28.4 | 32.2%              | 33.1% | 33.1% | 19.9% | 1.8               | 1.8  | 28.3 |
| Obesity-Y/N                                 | 15.5%                | 17.3% | 16.3% | 16.1% | 4.8               | 2.1  | 1.6  | 15.4%              | 15.5% | 15.0% | 16.1% | 0.1               | 1.2  | 1.9  |
| Use of other study medications-Y/N          | 3.1%                 | 0.5%  | 1.0%  | 0.8%  | 23.9              | 14.5 | 15.3 | 3.3%               | 2.0%  | 1.3%  | 0.8%  | 8.4               | 13.3 | 17.7 |
| Prescription for other anti-arrhythmics-Y/N | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.6               | 2.6  | 2.2  | 0.5%               | 0.4%  | 0.3%  | 0.4%  | 1.2               | 2.5  | 1.8  |
| Potentially hepatotoxic medication-Y/N      | 62.8%                | 69.7% | 63.5% | 56.5% | 14.8              | 1.4  | 13.0 | 63.2%              | 63.3% | 63.0% | 56.5% | 0.2               | 0.4  | 13.7 |
| Hospitalized-Y/N                            | 52.7%                | 78.9% | 67.4% | 40.6% | 60.1              | 30.4 | 24.3 | 52.9%              | 52.9% | 57.1% | 40.6% | 0.1               | 8.5  | 24.8 |
| Number of office visits (mean)              | 12.9                 | 12.1  | 11.9  | 11.4  | 8.4               | 10.8 | 16.2 | 12.9               | 12.8  | 12.5  | 11.4  | 1.3               | 4.8  | 17.0 |
| Visited ER-Y/N                              | 56.7%                | 62.2% | 60.5% | 56.2% | 11.1              | 7.6  | 1.2  | 56.5%              | 57.2% | 58.2% | 56.2% | 1.4               | 3.3  | 0.7  |
| Number of different medications (mean)      | 11.8                 | 12.9  | 11.5  | 9.5   | 19.3              | 3.6  | 38.6 | 11.7               | 12.0  | 11.6  | 9.5   | 4.4               | 2.0  | 38.6 |
| Gastroenterology specialty visits-Y/N       | 15.6%                | 15.7% | 14.5% | 12.8% | 0.3               | 2.9  | 8.0  | 15.3%              | 14.8% | 15.1% | 12.8% | 1.4               | 0.7  | 7.4  |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

## ILD Narrow Definition

**Table 11** through **Table 14** summarize the standardized differences between the MQ and comparator cohorts for the *ILD Narrow definition study population* and its corresponding PS-matched subsets under the four matching schemes tested.



**Table 11. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Narrow Definition Population vs. ILD Narrow Definition Analysis Dataset: DoD Database - 20 July 2009 to 30 September 2014 (Caliper=.2; 4,087 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                       | 46.5%                | 40.4% | 46.9% | 49.5% | 12.3              | 0.8  | 5.9  | 48.8%              | 48.5% | 47.5% | 49.4% | 0.6               | 2.6  | 1.2 |
| Age on index date (mean)                | 69.8                 | 73.2  | 70.5  | 63.7  | 35.9              | 7.5  | 52.1 | 67.3               | 69.6  | 70.1  | 66.7  | 21.9              | 26.7 | 5.7 |
| Study year of index date (mean)         | 2.5                  | 2.9   | 2.8   | 3.0   | 28.1              | 21.2 | 34.0 | 2.9                | 2.6   | 2.7   | 2.9   | 26.9              | 19.5 | 5.6 |
| Toxin exposure-Y/N                      | 0.3%                 | 0.4%  | 0.2%  | 0.3%  | 0.4               | 2.8  | 1.4  | 0.3%               | 0.1%  | 0.2%  | 0.3%  | 3.3               | 2.1  | 0.9 |
| Asthma-Y/N                              | 10.2%                | 9.7%  | 9.4%  | 10.2% | 1.7               | 2.7  | 0.0  | 9.4%               | 9.8%  | 9.7%  | 10.3% | 1.3               | 0.8  | 2.9 |
| COPD-Y/N                                | 17.1%                | 23.5% | 16.5% | 8.9%  | 15.6              | 1.5  | 23.7 | 12.9%              | 17.2% | 15.6% | 10.2% | 12.1              | 7.8  | 8.6 |
| Bronchitis-Y/N                          | 9.8%                 | 12.0% | 10.0% | 6.9%  | 6.9               | 0.6  | 10.1 | 7.6%               | 9.5%  | 9.7%  | 7.6%  | 6.7               | 7.5  | 0.0 |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.6               | 1.2  | 2.4  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.2               | 2.2  | 0.0 |
| Gastroesophageal Reflux-Y/N             | 28.5%                | 28.3% | 30.7% | 25.9% | 0.4               | 4.9  | 5.9  | 27.3%              | 28.1% | 28.6% | 27.6% | 1.9               | 2.9  | 0.7 |
| Connective Tissue Disease-Y/N           | 3.7%                 | 3.8%  | 4.0%  | 3.7%  | 0.4               | 1.3  | 0.3  | 3.6%               | 3.8%  | 3.6%  | 4.2%  | 1.0               | 0.1  | 2.8 |
| Hospitalized-Y/N                        | 49.4%                | 75.2% | 65.0% | 38.7% | 57.0              | 32.0 | 21.6 | 42.8%              | 44.9% | 52.9% | 40.9% | 4.4               | 20.4 | 3.9 |
| Potentially ILD inducing medication-Y/N | 92.8%                | 95.2% | 90.6% | 87.3% | 10.6              | 8.1  | 18.9 | 89.9%              | 92.8% | 92.0% | 90.1% | 10.1              | 7.3  | 0.5 |
| Pulmonology specialty visits-Y/N        | 14.1%                | 20.5% | 12.8% | 11.0% | 16.7              | 3.7  | 9.1  | 11.0%              | 11.9% | 13.4% | 11.6% | 2.6               | 7.2  | 1.7 |
| Other study drug-Y/N                    | 3.0%                 | 0.5%  | 0.9%  | 0.7%  | 22.2              | 14.5 | 16.0 | 0.7%               | 2.1%  | 1.4%  | 0.8%  | 11.4              | 6.2  | 1.1 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.3%  | 0.1               | 1.8  | 2.2  | 0.5%               | 0.5%  | 0.5%  | 0.4%  | 0.7               | 0.4  | 1.9 |
| Number of office visits (mean)          | 12.5                 | 11.8  | 11.8  | 11.2  | 8.5               | 8.5  | 15.0 | 11.2               | 12.2  | 12.0  | 11.7  | 12.1              | 10   | 6.6 |
| Visited ER-Y/N                          | 54.6%                | 58.3% | 58.1% | 55.5% | 7.5               | 7.2  | 1.8  | 53.7%              | 53.8% | 55.8% | 53.5% | 0.3               | 4.3  | 0.3 |
| Number of different medications (mean)  | 11.3                 | 12.3  | 11.1  | 9.3   | 18.0              | 2.5  | 36.1 | 10.0               | 11.2  | 11.1  | 9.8   | 21.1              | 20.9 | 2.3 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 12. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Narrow Definition Population vs. ILD Narrow Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=.1; 4,034 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                       | 46.5%                | 40.4% | 46.9% | 49.5% | 12.3              | 0.8  | 5.9  | 48.9%              | 48.6% | 47.5% | 49.2% | 0.5               | 2.7  | 0.6 |
| Age on index date (mean)                | 69.8                 | 73.2  | 70.5  | 63.7  | 35.9              | 7.5  | 52.1 | 67.3               | 69.7  | 70.1  | 66.7  | 22.3              | 26.3 | 5.9 |
| Study year of index date (mean)         | 2.5                  | 2.9   | 2.8   | 3.0   | 28.1              | 21.2 | 34.0 | 2.9                | 2.6   | 2.7   | 2.9   | 27.4              | 19.7 | 6.8 |
| Toxin exposure-Y/N                      | 0.3%                 | 0.4%  | 0.2%  | 0.3%  | 0.4               | 2.8  | 1.4  | 0.3%               | 0.1%  | 0.1%  | 0.3%  | 3.3               | 2.7  | 0.9 |
| Asthma-Y/N                              | 10.2%                | 9.7%  | 9.4%  | 10.2% | 1.7               | 2.7  | 0.0  | 9.4%               | 9.7%  | 9.6%  | 10.3% | 1.3               | 0.9  | 3.0 |
| COPD-Y/N                                | 17.1%                | 23.5% | 16.5% | 8.9%  | 15.6              | 1.5  | 23.7 | 12.9%              | 17.4% | 15.6% | 10.2% | 12.5              | 7.8  | 8.5 |
| Bronchitis-Y/N                          | 9.8%                 | 12.0% | 10.0% | 6.9%  | 6.9               | 0.6  | 10.1 | 7.6%               | 9.5%  | 9.7%  | 7.6%  | 6.8               | 7.5  | 0.2 |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.6               | 1.2  | 2.4  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.2               | 2.2  | 0.0 |
| Gastroesophageal Reflux-Y/N             | 28.5%                | 28.3% | 30.7% | 25.9% | 0.4               | 4.9  | 5.9  | 27.2%              | 28.4% | 28.7% | 27.7% | 2.5               | 3.3  | 0.9 |
| Connective Tissue Disease-Y/N           | 3.7%                 | 3.8%  | 4.0%  | 3.7%  | 0.4               | 1.3  | 0.3  | 3.6%               | 3.9%  | 3.5%  | 4.2%  | 1.2               | 0.5  | 2.7 |
| Hospitalized-Y/N                        | 49.4%                | 75.2% | 65.0% | 38.7% | 57.0              | 32.0 | 21.6 | 43.0%              | 45.0% | 52.9% | 41.0% | 4.1               | 20.1 | 4.0 |
| Potentially ILD inducing medication-Y/N | 92.8%                | 95.2% | 90.6% | 87.3% | 10.6              | 8.1  | 18.9 | 89.9%              | 92.8% | 91.9% | 90.0% | 10.4              | 7.1  | 0.3 |
| Pulmonology specialty visits-Y/N        | 14.1%                | 20.5% | 12.8% | 11.0% | 16.7              | 3.7  | 9.1  | 11.0%              | 11.9% | 13.4% | 11.6% | 2.7               | 7.3  | 1.9 |
| Other study drug-Y/N                    | 3.0%                 | 0.5%  | 0.9%  | 0.7%  | 22.2              | 14.5 | 16.0 | 0.7%               | 2.1%  | 1.4%  | 0.8%  | 11.4              | 6.1  | 1.1 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.3%  | 0.1               | 1.8  | 2.2  | 0.5%               | 0.5%  | 0.5%  | 0.4%  | 0.0               | 0.4  | 1.9 |
| Number of office visits (mean)          | 12.5                 | 11.8  | 11.8  | 11.2  | 8.5               | 8.5  | 15.0 | 11.2               | 12.2  | 12.0  | 11.7  | 11.9              | 10.0 | 6.7 |
| Visited ER-Y/N                          | 54.6%                | 58.3% | 58.1% | 55.5% | 7.5               | 7.2  | 1.8  | 53.7%              | 53.9% | 55.8% | 53.5% | 0.3               | 4.1  | 0.4 |
| Number of different medications (mean)  | 11.3                 | 12.3  | 11.1  | 9.3   | 18.0              | 2.5  | 36.1 | 9.9                | 11.2  | 11.1  | 9.9   | 21.6              | 21.3 | 1.4 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 13. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Narrow Definition Population vs. ILD Narrow Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=.05; 4,011 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |     |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|-----|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |     |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL  |
| Gender (% female)                       | 46.5%                | 40.4% | 46.9% | 49.5% | 12.3              | 0.8  | 5.9  | 48.9%              | 48.8% | 47.5% | 49.3% | 0.3               | 2.9  | 0.7 |
| Age on index date (mean)                | 69.8                 | 73.2  | 70.5  | 63.7  | 35.9              | 7.5  | 52.1 | 67.4               | 69.7  | 70.0  | 66.8  | 22.5              | 25.9 | 5.5 |
| Study year of index date (mean)         | 2.5                  | 2.9   | 2.8   | 3.0   | 28.1              | 21.2 | 34.0 | 2.9                | 2.6   | 2.7   | 2.8   | 26.8              | 18.7 | 6.8 |
| Toxin exposure-Y/N                      | 0.3%                 | 0.4%  | 0.2%  | 0.3%  | 0.4               | 2.8  | 1.4  | 0.3%               | 0.1%  | 0.1%  | 0.3%  | 3.2               | 3.2  | 0.0 |
| Asthma-Y/N                              | 10.2%                | 9.7%  | 9.4%  | 10.2% | 1.7               | 2.7  | 0.0  | 9.3%               | 9.8%  | 9.7%  | 10.2% | 1.4               | 1.2  | 2.9 |
| COPD-Y/N                                | 17.1%                | 23.5% | 16.5% | 8.9%  | 15.6              | 1.5  | 23.7 | 12.9%              | 17.4% | 15.8% | 10.1% | 12.7              | 8.3  | 8.7 |
| Bronchitis-Y/N                          | 9.8%                 | 12.0% | 10.0% | 6.9%  | 6.9               | 0.6  | 10.1 | 7.5%               | 9.6%  | 9.8%  | 7.7%  | 7.6               | 8.2  | 0.7 |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.6               | 1.2  | 2.4  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.2               | 2.2  | 0.0 |
| Gastroesophageal Reflux-Y/N             | 28.5%                | 28.3% | 30.7% | 25.9% | 0.4               | 4.9  | 5.9  | 27.3%              | 28.3% | 28.6% | 27.6% | 2.1               | 2.8  | 0.5 |
| Connective Tissue Disease-Y/N           | 3.7%                 | 3.8%  | 4.0%  | 3.7%  | 0.4               | 1.3  | 0.3  | 3.6%               | 3.9%  | 3.6%  | 4.1%  | 1.4               | 0.3  | 2.6 |
| Hospitalized-Y/N                        | 49.4%                | 75.2% | 65.0% | 38.7% | 57.0              | 32.0 | 21.6 | 43.4%              | 45.3% | 53.1% | 40.9% | 3.8               | 19.6 | 5.0 |
| Potentially ILD inducing medication-Y/N | 92.8%                | 95.2% | 90.6% | 87.3% | 10.6              | 8.1  | 18.9 | 89.9%              | 92.9% | 91.9% | 90.0% | 10.9              | 7.3  | 0.6 |
| Pulmonology specialty visits-Y/N        | 14.1%                | 20.5% | 12.8% | 11.0% | 16.7              | 3.7  | 9.1  | 11.0%              | 11.8% | 13.3% | 11.6% | 2.7               | 7.3  | 2.0 |
| Other study drug-Y/N                    | 3.0%                 | 0.5%  | 0.9%  | 0.7%  | 22.2              | 14.5 | 16.0 | 0.6%               | 2.0%  | 1.2%  | 0.8%  | 12.5              | 6.3  | 2.7 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.3%  | 0.1               | 1.8  | 2.2  | 0.5%               | 0.5%  | 0.5%  | 0.4%  | 1.0               | 0.0  | 1.5 |
| Number of office visits (mean)          | 12.5                 | 11.8  | 11.8  | 11.2  | 8.5               | 8.5  | 15.0 | 11.2               | 12.2  | 12.0  | 11.7  | 11.9              | 10.0 | 6.7 |
| Visited ER-Y/N                          | 54.6%                | 58.3% | 58.1% | 55.5% | 7.5               | 7.2  | 1.8  | 53.8%              | 53.9% | 56.0% | 53.4% | 0.2               | 4.5  | 0.6 |
| Number of different medications (mean)  | 11.3                 | 12.3  | 11.1  | 9.3   | 18.0              | 2.5  | 36.1 | 10.0               | 11.2  | 11.1  | 9.9   | 21.3              | 21.3 | 1.5 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 14. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Narrow Definition Population vs. ILD Narrow Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=Nearest Neighbor; 4,915 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL   |
| Gender (% female)                       | 46.5%                | 40.4% | 46.9% | 49.5% | 12.3              | 0.8  | 5.9  | 46.2%              | 47.3% | 47.2% | 49.5% | 2.2               | 2.0  | 6.6  |
| Age on index date (mean)                | 69.8                 | 73.2  | 70.5  | 63.7  | 35.9              | 7.5  | 52.1 | 69.8               | 70.5  | 70.1  | 63.7  | 6.8               | 2.5  | 50.8 |
| Study year of index date (mean)         | 2.5                  | 2.9   | 2.8   | 3.0   | 28.1              | 21.2 | 34.0 | 2.5                | 2.5   | 2.6   | 3.0   | 1.5               | 7.6  | 34.6 |
| Toxin exposure-Y/N                      | 0.3%                 | 0.4%  | 0.2%  | 0.3%  | 0.4               | 2.8  | 1.4  | 0.4%               | 0.2%  | 0.2%  | 0.3%  | 3.0               | 3.4  | 2.1  |
| Asthma-Y/N                              | 10.2%                | 9.7%  | 9.4%  | 10.2% | 1.7               | 2.7  | 0.0  | 9.7%               | 9.5%  | 9.6%  | 10.2% | 0.5               | 0.1  | 1.9  |
| COPD-Y/N                                | 17.1%                | 23.5% | 16.5% | 8.9%  | 15.6              | 1.5  | 23.7 | 17.0%              | 18.3% | 16.4% | 8.9%  | 3.3               | 1.5  | 24.3 |
| Bronchitis-Y/N                          | 9.8%                 | 12.0% | 10.0% | 6.9%  | 6.9               | 0.6  | 10.1 | 9.9%               | 10.2% | 10.1% | 6.9%  | 0.9               | 0.5  | 10.6 |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.6               | 1.2  | 2.4  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 1.2               | 1.2  | 2.9  |
| Gastroesophageal Reflux-Y/N             | 28.5%                | 28.3% | 30.7% | 25.9% | 0.4               | 4.9  | 5.9  | 28.2%              | 28.1% | 29.2% | 25.9% | 0.2               | 2.3  | 5.2  |
| Connective Tissue Disease-Y/N           | 3.7%                 | 3.8%  | 4.0%  | 3.7%  | 0.4               | 1.3  | 0.3  | 3.5%               | 4.1%  | 3.8%  | 3.7%  | 2.8               | 1.2  | 0.8  |
| Hospitalized-Y/N                        | 49.4%                | 75.2% | 65.0% | 38.7% | 57.0              | 32.0 | 21.6 | 50.1%              | 50.6% | 56.8% | 38.7% | 1.1               | 13.6 | 23.1 |
| Potentially ILD inducing medication-Y/N | 92.8%                | 95.2% | 90.6% | 87.3% | 10.6              | 8.1  | 18.9 | 92.7%              | 93.1% | 91.9% | 87.3% | 1.7               | 3.0  | 17.9 |
| Pulmonology specialty visits-Y/N        | 14.1%                | 20.5% | 12.8% | 11.0% | 16.7              | 3.7  | 9.1  | 14.1%              | 12.4% | 13.5% | 11.0% | 5.0               | 1.7  | 9.5  |
| Other study drug-Y/N                    | 3.0%                 | 0.5%  | 0.9%  | 0.7%  | 22.2              | 14.5 | 16.0 | 3.0%               | 1.9%  | 1.1%  | 0.7%  | 7.4               | 13.3 | 17.4 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.3%  | 0.1               | 1.8  | 2.2  | 0.4%               | 0.6%  | 0.4%  | 0.3%  | 2.8               | 0.3  | 1.3  |
| Number of office visits (mean)          | 12.5                 | 11.8  | 11.8  | 11.2  | 8.5               | 8.5  | 15.0 | 12.5               | 12.4  | 12.2  | 11.2  | 0.6               | 3.4  | 14.6 |
| Visited ER-Y/N                          | 54.6%                | 58.3% | 58.1% | 55.5% | 7.5               | 7.2  | 1.8  | 55.0%              | 56.0% | 57.7% | 55.5% | 2.0               | 5.4  | 1.0  |
| Number of different medications (mean)  | 11.3                 | 12.3  | 11.1  | 9.3   | 18.0              | 2.5  | 36.1 | 11.3               | 11.6  | 11.2  | 9.3   | 4.7               | 1.4  | 36.7 |

Abbreviations PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

## ILD Broad Definition

**Table 15** through **Table 18** summarize the standardized differences between the MQ and comparator cohorts for the *ILD Broad definition study population* and its corresponding PS-matched subsets under the four matching schemes tested.

**Table 15. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Broad Definition Population vs. ILD Broad Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=.2; 3,594 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL   |
| Gender (% female)                       | 45.7%                | 41.3% | 46.2% | 48.5% | 8.9               | 0.9  | 5.6  | 48.4%              | 48.2% | 46.7% | 49.2% | 0.6               | 3.4  | 1.5  |
| Age on index date (mean)                | 69.3                 | 73.4  | 70.1  | 63.2  | 41.9              | 7.9  | 51.2 | 67.2               | 69.0  | 69.7  | 66.7  | 16.9              | 23.7 | 5.2  |
| Study year of index date (mean)         | 2.6                  | 2.9   | 2.8   | 3.0   | 26.2              | 19.5 | 33.7 | 2.9                | 2.6   | 2.7   | 2.9   | 23.4              | 19.6 | 4.0  |
| Toxin exposure-Y/N                      | 0.1%                 | 0.2%  | 0.1%  | 0.2%  | 0.9               | 0.7  | 0.9  | 0.1%               | 0.1%  | 0.1%  | 0.2%  | 1.9               | 2.7  | 4.5  |
| Asthma-Y/N                              | 9.1%                 | 8.3%  | 8.4%  | 9.3%  | 2.6               | 2.4  | 0.8  | 8.7%               | 8.8%  | 8.5%  | 9.5%  | 0.7               | 0.5  | 2.8  |
| COPD-Y/N                                | 14.2%                | 18.5% | 13.8% | 7.2%  | 11.3              | 1.1  | 22.3 | 11.7%              | 14.7% | 13.0% | 8.1%  | 8.9               | 3.7  | 12.2 |
| Bronchitis-Y/N                          | 8.0%                 | 9.2%  | 8.1%  | 5.9%  | 4.5               | 0.7  | 8.0  | 6.9%               | 7.1%  | 8.0%  | 6.4%  | 0.9               | 4.2  | 2.1  |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.4               | 1.3  | 2.7  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.4               | 2.4  | 0.0  |
| Gastroesophageal Reflux-Y/N             | 27.0%                | 26.2% | 29.5% | 25.2% | 1.9               | 5.5  | 4.2  | 27.3%              | 27.9% | 28.8% | 26.5% | 1.2               | 3.3  | 1.8  |
| Connective Tissue Disease-Y/N           | 3.3%                 | 3.6%  | 3.6%  | 3.4%  | 1.6               | 2.0  | 0.5  | 3.1%               | 3.8%  | 3.6%  | 4.0%  | 3.7               | 2.9  | 4.7  |
| Hospitalized-Y/N                        | 44.6%                | 64.7% | 60.8% | 35.9% | 41.5              | 32.9 | 17.7 | 40.2%              | 42.2% | 49.1% | 38.0% | 4.0               | 17.9 | 4.5  |
| Potentially ILD inducing medication-Y/N | 92.4%                | 94.7% | 89.9% | 87.1% | 9.5               | 8.9  | 18.1 | 90.4%              | 92.7% | 91.6% | 90.3% | 8.2               | 4.1  | 0.2  |
| Pulmonology specialty visits-Y/N        | 11.1%                | 12.4% | 9.6%  | 9.3%  | 4.1               | 4.9  | 5.8  | 9.7%               | 12.1% | 9.3%  | 9.2%  | 7.7               | 1.5  | 1.9  |
| Other study drug-Y/N                    | 2.8%                 | 0.6%  | 0.9%  | 0.6%  | 19.1              | 13.9 | 15.9 | 0.5%               | 1.6%  | 1.2%  | 0.8%  | 10.8              | 7.0  | 3.1  |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.1               | 2.8  | 2.8  | 0.4%               | 0.6%  | 0.4%  | 0.4%  | 2.0               | 0.0  | 0.4  |
| Number of office visits (mean)          | 12.2                 | 11.6  | 11.4  | 10.8  | 6.7               | 9.0  | 15.8 | 10.8               | 12.0  | 11.8  | 11.4  | 13.5              | 11.8 | 6.6  |
| Visited ER-Y/N                          | 51.5%                | 56.2% | 55.5% | 53.6% | 9.3               | 7.9  | 4.1  | 50.1%              | 49.0% | 51.8% | 52.8% | 2.2               | 3.5  | 5.5  |
| Number of different medications (mean)  | 10.9                 | 11.8  | 10.7  | 9.0   | 15.8              | 3.1  | 35.3 | 9.8                | 10.8  | 10.7  | 9.6   | 18.4              | 16.9 | 3.2  |

Abbreviations: PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 16. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Broad Definition Population vs. ILD Broad Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=.1; 3,572 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                   |      |      | PS-Matched Subsets |       |       |       |                   |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-------------------|------|------|--------------------|-------|-------|-------|-------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/SD |      |      | Mean Value or %    |       |       |       | 100*Difference/SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                | SO   | FL   |
| Gender (% female)                       | 45.7%                | 41.3% | 46.2% | 48.5% | 8.9               | 0.9  | 5.6  | 48.3%              | 48.1% | 46.9% | 49.2% | 0.5               | 2.9  | 1.7  |
| Age on index date (mean)                | 69.3                 | 73.4  | 70.1  | 63.2  | 41.9              | 7.9  | 51.2 | 67.2               | 69.0  | 69.6  | 66.7  | 17.3              | 23.2 | 5.4  |
| Study year of index date (mean)         | 2.6                  | 2.9   | 2.8   | 3.0   | 26.2              | 19.5 | 33.7 | 2.9                | 2.6   | 2.7   | 2.9   | 23.6              | 20.3 | 5.1  |
| Toxin exposure-Y/N                      | 0.1%                 | 0.2%  | 0.1%  | 0.2%  | 0.9               | 0.7  | 0.9  | 0.1%               | 0.1%  | 0.1%  | 0.2%  | 1.9               | 2.7  | 4.5  |
| Asthma-Y/N                              | 9.1%                 | 8.3%  | 8.4%  | 9.3%  | 2.6               | 2.4  | 0.8  | 8.6%               | 8.7%  | 8.6%  | 9.4%  | 0.3               | 0.2  | 2.8  |
| COPD-Y/N                                | 14.2%                | 18.5% | 13.8% | 7.2%  | 11.3              | 1.1  | 22.3 | 11.6%              | 14.7% | 13.0% | 8.1%  | 9.2               | 4.4  | 11.6 |
| Bronchitis-Y/N                          | 8.0%                 | 9.2%  | 8.1%  | 5.9%  | 4.5               | 0.7  | 8.0  | 6.8%               | 7.3%  | 8.1%  | 6.4%  | 1.9               | 5.0  | 1.4  |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.4               | 1.3  | 2.7  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.4               | 2.4  | 0.0  |
| Gastroesophageal Reflux-Y/N             | 27.0%                | 26.2% | 29.5% | 25.2% | 1.9               | 5.5  | 4.2  | 27.1%              | 28.0% | 28.9% | 26.5% | 1.9               | 3.9  | 1.5  |
| Connective Tissue Disease-Y/N           | 3.3%                 | 3.6%  | 3.6%  | 3.4%  | 1.6               | 2.0  | 0.5  | 3.0%               | 3.8%  | 3.5%  | 4.0%  | 4.8               | 3.2  | 5.5  |
| Hospitalized-Y/N                        | 44.6%                | 64.7% | 60.8% | 35.9% | 41.5              | 32.9 | 17.7 | 40.3%              | 42.3% | 49.4% | 38.2% | 4.0               | 18.3 | 4.4  |
| Potentially ILD inducing medication-Y/N | 92.4%                | 94.7% | 89.9% | 87.1% | 9.5               | 8.9  | 18.1 | 90.2%              | 92.6% | 91.5% | 90.5% | 8.5               | 4.6  | 0.9  |
| Pulmonology specialty visits-Y/N        | 11.1%                | 12.4% | 9.6%  | 9.3%  | 4.1               | 4.9  | 5.8  | 9.8%               | 12.3% | 9.3%  | 9.3%  | 8.2               | 1.5  | 1.6  |
| Other study drug-Y/N                    | 2.8%                 | 0.6%  | 0.9%  | 0.6%  | 19.1              | 13.9 | 15.9 | 0.4%               | 1.7%  | 1.1%  | 0.8%  | 12.9              | 8.8  | 5.3  |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.1               | 2.8  | 2.8  | 0.4%               | 0.6%  | 0.4%  | 0.3%  | 2.4               | 0.0  | 1.4  |
| Number of office visits (mean)          | 12.2                 | 11.6  | 11.4  | 10.8  | 6.7               | 9.0  | 15.8 | 10.8               | 12.0  | 11.8  | 11.4  | 14.3              | 12.2 | 7.3  |
| Visited ER-Y/N                          | 51.5%                | 56.2% | 55.5% | 53.6% | 9.3               | 7.9  | 4.1  | 50.1%              | 48.9% | 51.7% | 52.9% | 2.2               | 3.3  | 5.6  |
| Number of different medications (mean)  | 10.9                 | 11.8  | 10.7  | 9.0   | 15.8              | 3.1  | 35.3 | 9.8                | 10.8  | 10.7  | 9.6   | 18.9              | 17.6 | 2.7  |

Abbreviations: PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 17. Standardized Differences in PS Model Covariates between Dronedaronone and Comparator Cohorts for ILD Broad Definition Population vs. ILD Broad Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=.05; 3,559 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                       |      |      | PS-Matched Subsets |       |       |       |                       |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-----------------------|------|------|--------------------|-------|-------|-------|-----------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/<br>SD |      |      | Mean Value or %    |       |       |       | 100*Difference/<br>SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                    | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                    | SO   | FL   |
| Gender (% female)                       | 45.7%                | 41.3% | 46.2% | 48.5% | 8.9                   | 0.9  | 5.6  | 48.4%              | 47.8% | 46.7% | 48.9% | 1.1                   | 3.3  | 1.0  |
| Age on index date (mean)                | 69.3                 | 73.4  | 70.1  | 63.2  | 41.9                  | 7.9  | 51.2 | 67.3               | 69.1  | 69.6  | 66.7  | 17.2                  | 22.8 | 5.7  |
| Study year of index date (mean)         | 2.6                  | 2.9   | 2.8   | 3.0   | 26.2                  | 19.5 | 33.7 | 2.9                | 2.6   | 2.7   | 2.9   | 23.8                  | 20.3 | 4.9  |
| Toxin exposure-Y/N                      | 0.1%                 | 0.2%  | 0.1%  | 0.2%  | 0.9                   | 0.7  | 0.9  | 0.1%               | 0.1%  | 0.1%  | 0.2%  | 1.9                   | 1.9  | 4.0  |
| Asthma-Y/N                              | 9.1%                 | 8.3%  | 8.4%  | 9.3%  | 2.6                   | 2.4  | 0.8  | 8.7%               | 8.6%  | 8.6%  | 9.4%  | 0.2                   | 0.2  | 2.6  |
| COPD-Y/N                                | 14.2%                | 18.5% | 13.8% | 7.2%  | 11.3                  | 1.1  | 22.3 | 11.7%              | 14.7% | 13.1% | 8.2%  | 9.0                   | 4.4  | 11.7 |
| Bronchitis-Y/N                          | 8.0%                 | 9.2%  | 8.1%  | 5.9%  | 4.5                   | 0.7  | 8.0  | 6.9%               | 7.2%  | 8.0%  | 6.5%  | 1.1                   | 4.1  | 1.8  |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.4                   | 1.3  | 2.7  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.4                   | 2.4  | 0.0  |
| Gastroesophageal Reflux-Y/N             | 27.0%                | 26.2% | 29.5% | 25.2% | 1.9                   | 5.5  | 4.2  | 27.4%              | 28.0% | 29.1% | 26.6% | 1.3                   | 3.7  | 1.9  |
| Connective Tissue Disease-Y/N           | 3.3%                 | 3.6%  | 3.6%  | 3.4%  | 1.6                   | 2.0  | 0.5  | 3.0%               | 3.8%  | 3.6%  | 4.0%  | 4.5                   | 3.2  | 5.4  |
| Hospitalized-Y/N                        | 44.6%                | 64.7% | 60.8% | 35.9% | 41.5                  | 32.9 | 17.7 | 40.5%              | 42.3% | 49.7% | 38.2% | 3.7                   | 18.6 | 4.7  |
| Potentially ILD inducing medication-Y/N | 92.4%                | 94.7% | 89.9% | 87.1% | 9.5                   | 8.9  | 18.1 | 90.1%              | 92.6% | 91.5% | 90.4% | 8.9                   | 5.0  | 0.9  |
| Pulmonology specialty visits-Y/N        | 11.1%                | 12.4% | 9.6%  | 9.3%  | 4.1                   | 4.9  | 5.8  | 9.7%               | 12.1% | 9.4%  | 9.2%  | 7.6                   | 1.1  | 1.7  |
| Other study drug-Y/N                    | 2.8%                 | 0.6%  | 0.9%  | 0.6%  | 19.1                  | 13.9 | 15.9 | 0.3%               | 1.6%  | 1.1%  | 0.8%  | 12.7                  | 9.0  | 5.7  |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.1                   | 2.8  | 2.8  | 0.4%               | 0.6%  | 0.4%  | 0.3%  | 2.3                   | 0.4  | 1.8  |
| Number of office visits (mean)          | 12.2                 | 11.6  | 11.4  | 10.8  | 6.7                   | 9.0  | 15.8 | 10.7               | 12.0  | 11.8  | 11.4  | 15.3                  | 12.6 | 8.0  |
| Visited ER-Y/N                          | 51.5%                | 56.2% | 55.5% | 53.6% | 9.3                   | 7.9  | 4.1  | 50.1%              | 48.7% | 51.6% | 53.0% | 2.9                   | 3.0  | 5.8  |
| Number of different medications (mean)  | 10.9                 | 11.8  | 10.7  | 9.0   | 15.8                  | 3.1  | 35.3 | 9.8                | 10.9  | 10.7  | 9.7   | 19.4                  | 17.1 | 2.7  |

Abbreviations: PS=Propensity Score, MQ=Dronedaronone, AM-Amiodaronone, SO=Sotalolol, FL=Flecainide



**Table 18. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Broad Definition Population vs. ILD Broad Definition Analysis Dataset: DoD Database - July 20, 2009 to September 30, 2014 (Caliper=Nearest Neighbor; 4,469 matches per cohort)**

|                                         | Prior to PS Matching |       |       |       |                       |      |      | PS-Matched Subsets |       |       |       |                       |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-----------------------|------|------|--------------------|-------|-------|-------|-----------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/<br>SD |      |      | Mean Value or %    |       |       |       | 100*Difference/<br>SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                    | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                    | SO   | FL   |
| Gender (% female)                       | 45.7%                | 41.3% | 46.2% | 48.5% | 8.9                   | 0.9  | 5.6  | 45.5%              | 46.9% | 46.1% | 48.5% | 2.8                   | 1.3  | 6.1  |
| Age on index date (mean)                | 69.3                 | 73.4  | 70.1  | 63.2  | 41.9                  | 7.9  | 51.2 | 69.3               | 69.9  | 69.8  | 63.2  | 5.9                   | 4.4  | 50.2 |
| Study year of index date (mean)         | 2.6                  | 2.9   | 2.8   | 3.0   | 26.2                  | 19.5 | 33.7 | 2.5                | 2.6   | 2.7   | 3.0   | 1.3                   | 8.3  | 34.1 |
| Toxin exposure-Y/N                      | 0.1%                 | 0.2%  | 0.1%  | 0.2%  | 0.9                   | 0.7  | 0.9  | 0.1%               | 0.1%  | 0.1%  | 0.2%  | 0.0                   | 0.6  | 1.8  |
| Asthma-Y/N                              | 9.1%                 | 8.3%  | 8.4%  | 9.3%  | 2.6                   | 2.4  | 0.8  | 8.7%               | 8.7%  | 8.9%  | 9.3%  | 0.0                   | 0.6  | 1.9  |
| COPD-Y/N                                | 14.2%                | 18.5% | 13.8% | 7.2%  | 11.3                  | 1.1  | 22.3 | 14.1%              | 15.4% | 13.6% | 7.2%  | 3.4                   | 1.6  | 22.8 |
| Bronchitis-Y/N                          | 8.0%                 | 9.2%  | 8.1%  | 5.9%  | 4.5                   | 0.7  | 8.0  | 7.9%               | 7.7%  | 8.1%  | 5.9%  | 0.5                   | 1.0  | 7.7  |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.4                   | 1.3  | 2.7  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 1.2                   | 1.2  | 3.0  |
| Gastroesophageal Reflux-Y/N             | 27.0%                | 26.2% | 29.5% | 25.2% | 1.9                   | 5.5  | 4.2  | 27.1%              | 27.1% | 28.7% | 25.2% | 0.1                   | 3.5  | 4.4  |
| Connective Tissue Disease-Y/N           | 3.3%                 | 3.6%  | 3.6%  | 3.4%  | 1.6                   | 2.0  | 0.5  | 3.4%               | 3.7%  | 3.6%  | 3.4%  | 1.6                   | 1.3  | 0.1  |
| Hospitalized-Y/N                        | 44.6%                | 64.7% | 60.8% | 35.9% | 41.5                  | 32.9 | 17.7 | 44.1%              | 45.4% | 55.5% | 35.9% | 2.5                   | 22.9 | 16.9 |
| Potentially ILD inducing medication-Y/N | 92.4%                | 94.7% | 89.9% | 87.1% | 9.5                   | 8.9  | 18.1 | 92.4%              | 93.0% | 91.0% | 87.1% | 2.3                   | 5.2  | 17.5 |
| Pulmonology specialty visits-Y/N        | 11.1%                | 12.4% | 9.6%  | 9.3%  | 4.1                   | 4.9  | 5.8  | 11.0%              | 12.3% | 9.5%  | 9.3%  | 3.9                   | 5.1  | 5.6  |
| Other study drug-Y/N                    | 2.8%                 | 0.6%  | 0.9%  | 0.6%  | 19.1                  | 13.9 | 15.9 | 2.8%               | 1.5%  | 1.0%  | 0.6%  | 8.7                   | 12.9 | 16.5 |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.1                   | 2.8  | 2.8  | 0.5%               | 0.6%  | 0.4%  | 0.4%  | 1.5                   | 2.3  | 2.7  |
| Number of office visits (mean)          | 12.2                 | 11.6  | 11.4  | 10.8  | 6.7                   | 9.0  | 15.8 | 12.1               | 12.2  | 11.7  | 10.8  | 1.0                   | 4.6  | 15.5 |
| Visited ER-Y/N                          | 51.5%                | 56.2% | 55.5% | 53.6% | 9.3                   | 7.9  | 4.1  | 51.3%              | 50.0% | 54.0% | 53.6% | 2.6                   | 5.3  | 4.6  |
| Number of different medications (mean)  | 10.9                 | 11.8  | 10.7  | 9.0   | 15.8                  | 3.1  | 35.3 | 10.9               | 11.2  | 10.8  | 9.0   | 5.3                   | 1.6  | 35.3 |

Abbreviations: PS=Propensity Score, MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

## F. VALIDATE PROPENSITY SCORE BALANCE ON ILD NARROW DEFINITION OUTCOME

Test of Non-significant Interaction between PS and Cohort

The p-value for the Cohort \* PS interaction terms (shown in the following tables) should be well above 0.05 for all comparator cohorts.

### Comparator=Amiodarone

| Parameter                 | Hazard Ratio | 95% CI    | p-value |
|---------------------------|--------------|-----------|---------|
| Cohort                    | 2.8          | 1.2 - 6.6 | 0.02    |
| Study Year                | 1.2          | 0.8 - 1.7 | 0.3     |
| Propensity Score          | 0.7          | 0.3 - 1.8 | 0.5     |
| Cohort * Propensity Score | 1.5          | 0.5 - 3.9 | 0.5     |

### Comparator=Sotalol

| Parameter                 | Hazard Ratio | 95% CI    | p-value |
|---------------------------|--------------|-----------|---------|
| Cohort                    | 0.6          | 0.2 - 2.5 | 0.5     |
| Age                       | 1.1          | 1.0 - 1.1 | 0.03    |
| Propensity Score          | 1.1          | 0.3 - 4.4 | 0.9     |
| Cohort * Propensity Score | 1.8          | 0.3 - 12  | 0.6     |

### Comparator=Flecainide

| Parameter                 | Hazard Ratio | 95% CI    | p-value |
|---------------------------|--------------|-----------|---------|
| Cohort                    | 0.7          | 0.2 - 3.3 | 0.7     |
| Propensity Score          | 1.7          | 0.6 - 4.7 | 0.3     |
| Cohort * Propensity Score | 1.6          | 0.4 - 6.1 | 0.5     |

## G. TEST CONSTANCY OF HAZARD RATIO ACROSS PS-QUINTILES FOR EACH COHORT

Within each cohort, the hazard ratio should not vary systematically across the five PS-based strata (Q1 – Q5). They should fluctuate randomly, over a range consistent with their precision (as indicated by their confidence intervals: Lo – Hi). In other words, the hazard ratios should not show a steady trend across the quintiles, and the CIs should largely overlap. These data are also displayed in a forest plot on the next page.

### Comparator=Amiodarone

| Quintile | Hazard Ratio | 95% CI    | pValue |
|----------|--------------|-----------|--------|
| Q1       | 1.4          | 0.2 - 8.6 | 0.7    |
| Q2       | 1.8          | 0.3 - 9.8 | 0.5    |
| Q3       | 3.0          | 0.3 - 27  | 0.3    |
| Q4       | 2.4          | 0.5 - 12  | 0.3    |
| Q5       | 3.6          | 0.8 - 18  | 0.1    |

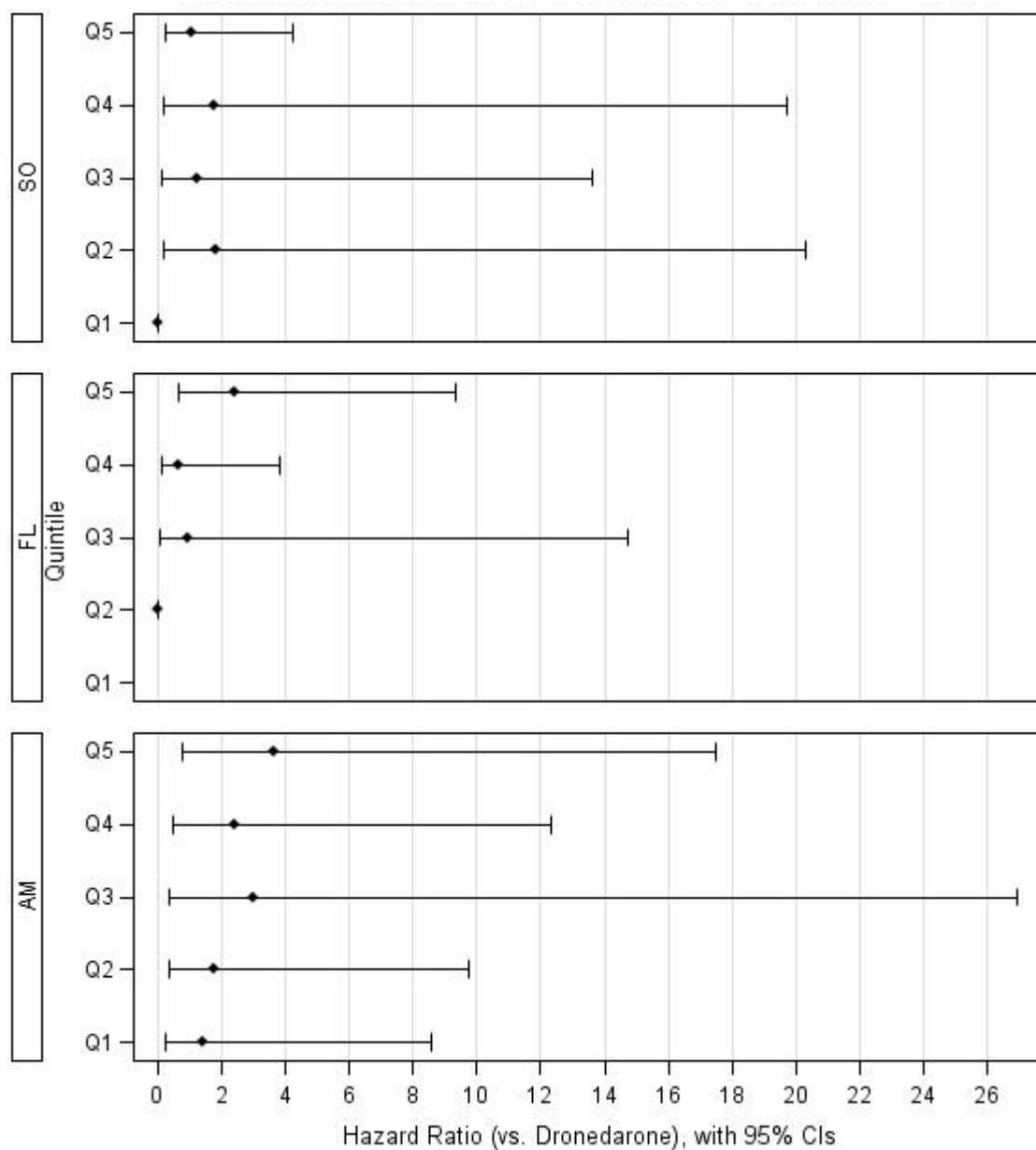
### Comparator=Sotalol

| Quintile | Hazard Ratio | 95% CI    | pValue |
|----------|--------------|-----------|--------|
| Q1       | 0.0          | 0.0 - .   | 1.0    |
| Q2       | 1.8          | 0.2 - 20  | 0.6    |
| Q3       | 1.2          | 0.1 - 14  | 0.9    |
| Q4       | 1.8          | 0.2 - 20  | 0.6    |
| Q5       | 1.1          | 0.3 - 4.2 | 0.9    |

### Comparator=Flecainide

| Quintile | Hazard Ratio | 95% CI    | pValue |
|----------|--------------|-----------|--------|
| Q1       | .            | . - .     | .      |
| Q2       | 0.0          | 0.0 - .   | 1.0    |
| Q3       | 0.9          | 0.1 - 15  | 1.0    |
| Q4       | 0.6          | 0.1 - 3.8 | 0.6    |
| Q5       | 2.4          | 0.6 - 9.3 | 0.2    |

# **Forest Plot ILD Narrow Definition to End of Follow-up** **Hazard Ratio vs. Dronedarone by Comparator Cohort and PS Quintile**



## APPENDIX 13: ILD SENSITIVITY ANALYSES

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## A. ILD SENSITIVITY ANALYSES

Three sensitivity analyses were conducted for the ILD outcome In order to address complexities of definition and outcome latency associated with ILD. Those separate analyses varied from the primary ILD analysis of this study by changing the definition of ILD used for baseline screening and outcome identification, and/or the risk period examined for ILD outcomes.

Comparisons of demographic characteristics and medical history of patients with confirmed ILD outcomes are provided for each sensitivity analysis, along with comparisons of the outcome rates.

## B. DEFINITIONS OF ILD FOR EXCLUSIONARY SCREENING AND OUTCOME EVENT IDENTIFICATION IN SENSITIVITY ANALYSES

The ILD sensitivity analyses used two different definitions of ILD. The two definitions are referred to as the ILD Narrow definition and the ILD Broad definition.

### ILD Narrow

The ILD Narrow definition was used in the primary ILD analysis and ILD Sensitivity analysis 1. Cohort screening and outcome event definitions are described in sections 8.3.3.2 and 8.4.5.2 of the main report.

### ILD Broad

The ILD Broad definition was used in ILD Sensitivity analyses 2 and 3. Cohort screening and outcome event definitions are described below.

#### ***ILD Broad Definition Exclusionary Screening***

To create the ILD Broad definition study cohorts, patients in the Final study drug cohorts with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) of the following diseases were excluded:

- History of Interstitial lung disease Broad definition;
- History of pneumonia; or
- History of sarcoidosis.

Specific codes used to identify the conditions used as screening criteria for the ILD Broad definition population are described below.

#### **History of Interstitial Lung Disease Broad definition**

495.9 Unspecified allergic alveolitis and pneumonitis

515 Post-inflammatory pulmonary fibrosis

- 516.3 Idiopathic fibrosing alveolitis
- 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
- 516.31 Idiopathic pulmonary fibrosis (IPF)
- 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
- 516.33 Acute interstitial pneumonitis (AIP)
- 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
- 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
- 516.36 Cryptogenic organizing pneumonia (COP)
- 516.37 Desquamative interstitial pneumonia (DIP)
- 516.8 Other specified alveolar and parietoalveolar pneumonopathies
- 516.9 Unspecified alveolar and parietoalveolar pneumonopathy
- 518 Other diseases of lung
- 518.0 Pulmonary collapse
- 518.1 Interstitial emphysema
- 518.2 Compensatory emphysema
- 518.3 Pulmonary eosinophilia
- 518.4 Acute edema of lung unspecified
- 518.5 Pulmonary insufficiency following trauma and surgery
- 518.51 Acute respiratory failure following trauma and surgery
- 518.52 Other pulmonary insufficiency NEC following trauma and surgery
- 518.53 Acute and chronic respiratory failure following trauma and surgery
- 518.6 Allergic bronchopulmonary aspergilliosis
- 518.7 Transfusion related acute lung injury (trali)
- 518.8 Other diseases of lung
- 518.81 Acute respiratory failure
- 518.82 Other pulmonary insufficiency not elsewhere classified
- 518.83 Chronic respiratory failure
- 518.84 Acute and chronic respiratory failure
- 518.89 Other diseases of lung not elsewhere classified

### **History of Pneumonia**

- 480 Viral Pneumonia
- 480.0 Pneumonia Due To Adenovirus
- 480.1 Pneumonia Due To Respiratory Syncytial Virus
- 480.2 Pneumonia Due To Parainfluenza Virus
- 480.3 Pneumonia Due To Sars-Associated Coronavirus
- 480.8 Pneumonia Due To Other Virus Not Elsewhere Classified
- 480.9 Viral Pneumonia Unspecified
- 481 Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia]
- 482 Other Bacterial Pneumonia
- 482.0 Pneumonia Due To Klebsiella Pneumoniae
- 482.1 Pneumonia Due To Pseudomonas
- 482.2 Pneumonia Due To Hemophilus Influenzae (H. Influenzae)
- 482.3 Pneumonia Due To Streptococcus
- 482.30 Pneumonia Due To Streptococcus Unspecified
- 482.31 Pneumonia Due To Streptococcus Group A
- 482.32 Pneumonia Due To Streptococcus Group B
- 482.39 Pneumonia Due To Other Streptococcus

482.4 Pneumonia Due To Staphylococcus  
 482.40 Pneumonia Due To Staphylococcus Unspecified  
 482.41 Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus  
 482.42 Methicillin Resistant Pneumonia Due To Staphylococcus Aureus  
 482.49 Other Staphylococcus Pneumonia  
 482.8 Pneumonia Due To Other Specified Bacteria  
 482.81 Pneumonia Due To Anaerobes  
 482.82 Pneumonia Due To Escherichia Coli [E.Coli]  
 482.83 Pneumonia Due To Other Gram-Negative Bacteria  
 482.84 Pneumonia Due To Legionnaires' Disease  
 482.89 Pneumonia Due To Other Specified Bacteria  
 482.9 Bacterial Pneumonia Unspecified  
 483.8 Pneumonia Due To Other Specified Organism  
 485 Bronchopneumonia Organism Unspecified  
 486 Pneumonia Organism Unspecified  
 487.0 Influenza With Pneumonia  
 507.0 Pneumonitis due to inhalation of food or vomitus  
 V12.61 Personal History Of Pneumonia (Recurrent)

#### **History of Sarcoidosis**

135 Sarcoidosis

---

NEC = not elsewhere classified



**Table 1. ILD Broad Cohort Screening Results**

| <b>Interstitial Lung Disease (ILD) Broad<br/>(Sensitivity Analysis)</b> | <b>Dronedarone</b> |          | <b>Amiodarone</b> |          | <b>Sotalol</b> |          | <b>Flecainide</b> |          | <b>Dofetilide</b> |          | <b>Propafenone</b> |          |
|-------------------------------------------------------------------------|--------------------|----------|-------------------|----------|----------------|----------|-------------------|----------|-------------------|----------|--------------------|----------|
|                                                                         | <b>#</b>           | <b>%</b> | <b>#</b>          | <b>%</b> | <b>#</b>       | <b>%</b> | <b>#</b>          | <b>%</b> | <b>#</b>          | <b>%</b> | <b>#</b>           | <b>%</b> |
| Remaining patients prior to screening for Outcome Cohorts               | 9,414              | 59.3     | 24,885            | 34.3     | 7,299          | 27.2     | 5,328             | 33.1     | 945               | 30.6     | 3,519              | 29.9     |
| Less patients with ILD (Broad) in baseline period                       | 2,467              | 15.5     | 13,260            | 18.3     | 2,216          | 8.3      | 859               | 5.3      | 282               | 9.1      | 756                | 6.4      |
| Study Cohorts for ILD (Broad) Outcome Analysis                          | 6,947              | 43.7     | 11,625            | 16.0     | 5,083          | 19.0     | 4,469             | 27.7     | 663               | 21.5     | 2,763              | 23.5     |
| Patients with ILD (Broad) Outcome, Risk Period 1                        | 66                 | 0.4      | 147               | 0.2      | 43             | 0.16     | 23                | 0.14     | 6                 | 0.19     | 12                 | 0.10     |
| Patients with ILD (Broad) Outcome, Risk Period 2                        | 13                 | 0.08     | 48                | 0.07     | 14             | 0.05     | 4                 | 0.02     | 2                 | 0.06     | 3                  | 0.03     |

The 31,550 patients remaining after the ILD Broad definition exclusionary screening formed the *ILD Broad definition study population*. ([Table 1](#)) Propensity score matching, as described in [Appendix 12](#), was then applied to the *ILD Broad definition study population* to generate the *ILD Broad definition analysis dataset*.

### ***ILD Broad Definition Outcome Events***

ILD Broad definition outcome events were identified from a list of ICD-9-CM codes that included all those used to define the ILD Narrow definition outcomes, plus ICD-9CM codes 495.9 and 518.82. The complete list is provided below.

For each patient in the ILD Broad definition cohorts, the first hospitalization with a discharge diagnosis code meeting the ILD Broad outcome definition within the relevant ILD risk period (see [Sensitivity Analyses Parameters](#), below) was identified as the suspect ILD outcome event. The ILD defining diagnosis code could appear anywhere among the facility discharge diagnoses (i.e., it did not have to be the primary discharge diagnosis). The admission date of the hospitalization with the ILD defining code was assigned as the suspect ILD outcome event date.

ILD Broad definition outcomes were defined using the codes listed below.

#### **ILD Broad Definition - ICD-9-CM Diagnosis Codes**

|        |                                                                                                     |
|--------|-----------------------------------------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                                                     |
| 515    | Post-inflammatory pulmonary fibrosis                                                                |
| 516.3  | Idiopathic fibrosing alveolitis                                                                     |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP)                                    |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                                                                 |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)                                             |
| 516.33 | Acute interstitial pneumonitis (AIP)                                                                |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)                                        |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                                                    |
| 516.36 | Cryptogenic organizing pneumonia (COP)                                                              |
| 516.37 | Desquamative interstitial pneumonia (DIP)                                                           |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies                                        |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy                                              |
| 518.82 | Other pulmonary insufficiency, not elsewhere classified (e.g., adult respiratory distress syndrome) |

As with the ILD Narrow definition codes, none of the ICD-9-CM codes listed above have been validated.

## C. ILD BROAD DEFINITION DATASETS

*Sensitivity Analysis 2 and Sensitivity Analysis 3 were based on the ILD Broad definition study population. Separate propensity score matching was conducted to construct the ILD Broad definition analysis dataset. Characteristics of patients in the overall ILD Broad definition study population and the PS-matched ILD Broad definition analysis dataset are provided below.*

### **Characteristics of Patients in the *ILD Broad Definition Study Population* Prior to Propensity Score Matching**

#### ***Baseline Characteristics***

Baseline demographic characteristics, and medical and medication use histories for all patients meeting the *ILD broad definition study population* inclusion criteria are found in [Table 2](#). Following initial cohort screening and specific screening for baseline diagnoses consistent with the broad definition of ILD, 31,550 patients remained in the *ILD Broad definition study population*. The amiodarone cohort comprised the largest single subgroup, accounting for roughly one third of the population (36.8%). One fifth of the ILD broad definition patients fell in the dronedarone cohort (22.0%), and another third were divided fairly evenly between the sotalol and flecainide cohorts (16.1% and 14.2%, respectively). The dofetilide and propafenone cohorts together accounted for less than 10% of patients screened into the *ILD Broad definition study population*, and neither met the minimum number required by the study's power calculations for inclusion in the analysis dataset.

#### ***Demographic Characteristics***

The average age of patients in the broad definition study population fell between 63.2 years and 73.4 years. Flecainide patients had the youngest mean age, while the amiodarone patients were oldest, on average.

Roughly half the patients were female in the dronedarone, sotalol, flecainide and propafenone cohorts (45.7%, 46.2%, 48.5% and 50.5%, respectively). The amiodarone and dofetilide cohorts were less balanced by gender, with 41.3% and 31.8% of those cohorts, respectively, accounted for by females.

Race was unknown for roughly half the patients in each *ILD broad definition study population* cohort. The majority of patients with known race were White (between 84% and 88% of each cohort) and between 5.6% and 8.0% were Black. Other racial groups, combined, accounted for less than 8% of patients with known race in any cohort.

**Table 2. Baseline Characteristics of Patients in the ILD Broad Definition Study Population according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                            | Dronedarone  |            | Amiodarone    |            | Sotalol      |            | Flecainide   |            | Dofetilide |            | Propafenone  |            |
|--------------------------------------------|--------------|------------|---------------|------------|--------------|------------|--------------|------------|------------|------------|--------------|------------|
| Characteristics, N %                       | N            | %          | N             | %          | N            | %          | N            | %          | N          | %          | N            | %          |
| <b>All Patients</b>                        | <b>6,947</b> | <b>100</b> | <b>11,625</b> | <b>100</b> | <b>5,083</b> | <b>100</b> | <b>4,469</b> | <b>100</b> | <b>663</b> | <b>100</b> | <b>2,763</b> | <b>100</b> |
| <b>Demographics</b>                        |              |            |               |            |              |            |              |            |            |            |              |            |
| Age at cohort entry date, Mean (SD)        | 69.3         | 10.5       | 73.4          | 9.4        | 70.1         | 10.2       | 63.2         | 13.7       | 67.8       | 10.1       | 66.6         | 12.0       |
| 18-39 years                                | 85           | 1.2        | 43            | 0.4        | 54           | 1.1        | 322          | 7.2        | 9          | 1.4        | 86           | 3.1        |
| 40-49 years                                | 229          | 3.3        | 134           | 1.2        | 138          | 2.7        | 385          | 8.6        | 20         | 3.0        | 170          | 6.2        |
| 50-59 years                                | 754          | 10.9       | 723           | 6.2        | 449          | 8.8        | 698          | 15.6       | 90         | 13.6       | 348          | 12.6       |
| 60-69 years                                | 2,199        | 31.7       | 2,704         | 23.3       | 1,582        | 31.1       | 1,492        | 33.4       | 229        | 34.5       | 942          | 34.1       |
| 70-79 years                                | 2,552        | 36.7       | 4,502         | 38.7       | 1,934        | 38.0       | 1,155        | 25.8       | 248        | 37.4       | 872          | 31.6       |
| 80+ years                                  | 1,128        | 16.2       | 3,519         | 30.3       | 926          | 18.2       | 417          | 9.3        | 67         | 10.1       | 345          | 12.5       |
| Gender (female)                            | 3,176        | 45.7       | 4,803         | 41.3       | 2,346        | 46.2       | 2,169        | 48.5       | 211        | 31.8       | 1,395        | 50.5       |
| Race                                       |              |            |               |            |              |            |              |            |            |            |              |            |
| White                                      | 2,471        | 35.6       | 3,412         | 29.4       | 1,639        | 32.2       | 1,851        | 41.4       | 301        | 45.4       | 1,010        | 36.6       |
| Asian or Pacific Islander                  | 67           | 1.0        | 147           | 1.3        | 51           | 1.0        | 64           | 1.4        | 7          | 1.1        | 27           | 1.0        |
| Black                                      | 175          | 2.5        | 304           | 2.6        | 113          | 2.2        | 177          | 4.0        | 19         | 2.9        | 78           | 2.8        |
| American Indian/Alaskan Native             | 12           | 0.2        | 16            | 0.14       | 8            | 0.2        | 9            | 0.2        | 2          | 0.3        | 6            | 0.2        |
| Two races reported                         | 29           | 0.4        | 31            | 0.3        | 20           | 0.4        | 36           | 0.8        | 2          | 0.3        | 15           | 0.5        |
| Other                                      | 88           | 1.3        | 121           | 1.0        | 44           | 0.9        | 63           | 1.4        | 11         | 1.7        | 22           | 0.8        |
| Unknown                                    | 4,105        | 59.1       | 7,594         | 65.3       | 3,208        | 63.1       | 2,269        | 50.8       | 321        | 48.4       | 1,605        | 58.1       |
| <b>History of Disease</b>                  |              |            |               |            |              |            |              |            |            |            |              |            |
| Deyo-Charlson Index, Mean (SD)             | 1.3          | 1.5        | 1.8           | 1.8        | 1.3          | 1.5        | 0.8          | 1.2        | 1.3        | 1.5        | 0.9          | 1.3        |
| Asthma                                     | 630          | 9.1        | 969           | 8.3        | 426          | 8.4        | 415          | 9.3        | 69         | 10.4       | 223          | 8.1        |
| Bronchitis                                 | 553          | 8.0        | 1,074         | 9.2        | 414          | 8.1        | 264          | 5.9        | 59         | 8.9        | 172          | 6.2        |
| Chronic Obstructive Pulmonary Disease      | 988          | 14.2       | 2,145         | 18.5       | 703          | 13.8       | 320          | 7.2        | 97         | 14.6       | 280          | 10.1       |
| Connective Tissue Disease                  | 228          | 3.3        | 415           | 3.6        | 185          | 3.6        | 151          | 3.4        | 18         | 2.7        | 87           | 3.1        |
| Exposure to Toxins                         | 10           | 0.14       | 21            | 0.2        | 6            | 0.12       | 8            | 0.2        | 3          | 0.5        | 10           | 0.4        |
| Gastroesophageal Reflux Disease            | 1,877        | 27.0       | 3,041         | 26.2       | 1,500        | 29.5       | 1,125        | 25.2       | 184        | 27.8       | 713          | 25.8       |
| <b>History of Medication Use</b>           |              |            |               |            |              |            |              |            |            |            |              |            |
| Other Anti-arrhythmic Agents               | 38           | 0.5        | 63            | 0.5        | 18           | 0.4        | 16           | 0.4        | 4          | 0.6        | 19           | 0.7        |
| Agents assoc w drug-induced pulmonary dis. | 6,420        | 92.4       | 11,008        | 94.7       | 4,571        | 89.9       | 3,892        | 87.1       | 622        | 93.8       | 2,374        | 85.9       |
| Therapeutic Oxygen Treatment               | 3            | 0.04       | 1             | 0.01       | 1            | 0.02       | 0            | 0.0        | 0          | 0.0        | 0            | 0.0        |

### *History of Disease*

Mean DCI scores for the *ILD Broad definition Study population* ranged from 0.8 in the flecainide cohort to 1.8 in the amiodarone cohort.

Of the medical conditions reported in [Table 2](#), GERD was the most frequently occurring in each cohort. Proportions of patients with GERD diagnoses were consistent across patient groups, being found in 25.2% to 29.5% of patient baseline records by cohort.

COPD was the second most frequently found medical condition in all except the flecainide cohort. Roughly one fifth (18.5%) of the amiodarone cohort and 14% of dronedarone, sotalol and dofetilide cohorts were found to have this diagnosis. Only 10.1% of the propafenone cohort and 7.2% of the flecainide cohort had COPD diagnoses in the baseline period.

Asthma diagnoses were found in baseline records of roughly 8% to 10% of patients in the *ILD Broad definition Study population*, and bronchitis in records of roughly 6% to 9% of patients. Less than 4% of any cohort had baseline records indicating connective tissue disease or exposure to toxins.

### *History of Medication Use*

Most patients in the *ILD Broad definition Study population* cohorts had baseline pharmacy records indicating that they were dispensed at least one medication potentially associated with drug-induced pulmonary disease. Propafenone patients were least likely to have received one of these drugs (85.9%) and amiodarone patients most likely (94.7%). The single largest group of potentially pulmonary toxic drugs dispensed during the baseline period to patients in the *ILD Broad definition Study population* were beta-blockers, found in the records of 34.8% of the group. Nearly one third of the population (30%) had been dispensed an anticoagulant prior to their index date, and about one fifth (18.7%) had record of ace inhibitors. Hydrochlorothiazide (or combination products containing hydrochlorothiazide) were found in baseline dispensing records of 11.6% of the group, and nitrofurantoin in the records of 2.1%. All other potentially ILD inducing drugs in the baseline records of the *Broad definition Study population* were found in records of less than 2% of the group.

Between 0.4% and 0.7% of patients in any cohort used other anti-arrhythmic agents in the year preceding their index date. The five patients with therapeutic oxygen treatments in the baseline period were accounted for by three dronedarone patients and one each in the amiodarone and sotalol cohorts.

## **Post-Index Date Characteristics**

### ***Patient Follow-Up Time***

The distribution of patients in the *ILD Broad definition Study population* according to length of follow-up are provided in [Table 3](#). Follow-up time was defined previously in [Section 8.4.2](#) of the main report.

The average follow-up time in this population ranged from approximately 30 months in the amiodarone cohort to 36.7 months in the dronedarone cohort. Average follow-up times in the sotalol, flecainide, dofetilide, and propafenone cohorts fell within a three-month range of 32.5 to 35.5 months.

### ***Length of Index Treatment Episode***

Index treatment episodes in the *ILD Broad definition Study population* were the same, or slightly longer, on average, than those of the corresponding cohorts in the *ILD Narrow definition Study population*. [Table 4](#) shows that mean index treatment episodes varied from 221 days (7.4 months) in the amiodarone cohort, to more than double that length in the dofetilide cohort (453 days or 15.1 months). The shortest index treatment episode lasted one day in all cohorts, and the longest exceeded five years.

### ***Number of Index Drug Treatment Episodes***

Patients in the *ILD Broad definition study population* averaged between one and two episodes of treatment with their index drug during the follow-up period. The median of one episode in all cohorts reflects the large proportion of patients (minimum two-thirds in each cohort) who had only one episode of treatment with their index drug. ([Table 5](#)) The maximum number of index drug treatment episodes ranged from 10 in the dofetilide cohort to a high of 19 in the sotalol cohort.

### ***Non-index Study Drugs Dispensed***

Also seen in [Table 5](#) is the distribution of patients in the *ILD Broad definition study population* cohorts according to the number of other study drugs dispensed during follow-up. Like patients in the *ILD narrow definition study population*, most of this group were not dispensed any study drugs other than the one that qualified them for inclusion in their drug cohort. The highest proportions of patients dispensed at least one study drug, other than their index drug, were found in the dronedarone and propafenone cohorts (34.1% and 33.5%, respectively). Patients in the amiodarone cohort were least likely to have filled a prescription for one of the other study drugs (13.0%).

**Table 3. ILD Broad Definition Study Population Follow-up Time according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            | <b>Dofetilide</b> |            | <b>Propafenone</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|--------------------|------------|
| <b>Follow-up Time<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>           | <b>%</b>   |
| <b>All Patients</b>               | <b>6,947</b>       | <b>100</b> | <b>11,625</b>     | <b>100</b> | <b>5,083</b>   | <b>100</b> | <b>4,469</b>      | <b>100</b> | <b>663</b>        | <b>100</b> | <b>2,763</b>       | <b>100</b> |
| 1-90 days                         | 63                 | 0.9        | 325               | 2.8        | 53             | 1.0        | 19                | 0.4        | 1                 | 0.2        | 23                 | 0.8        |
| 91-180 days                       | 42                 | 0.6        | 302               | 2.6        | 44             | 0.9        | 23                | 0.5        | 4                 | 0.6        | 17                 | 0.6        |
| 181-365 days                      | 556                | 8.0        | 1,630             | 14.0       | 560            | 11.0       | 590               | 13.2       | 77                | 11.6       | 262                | 9.5        |
| 366-545 days                      | 579                | 8.3        | 1,413             | 12.2       | 530            | 10.4       | 522               | 11.7       | 68                | 10.3       | 261                | 9.5        |
| 546-730 days                      | 578                | 8.3        | 1,286             | 11.1       | 598            | 11.8       | 516               | 11.6       | 77                | 11.6       | 267                | 9.7        |
| >730 days                         | 5,129              | 73.8       | 6,669             | 57.4       | 3,298          | 64.9       | 2,799             | 62.6       | 436               | 65.8       | 1,933              | 70.0       |
| Mean                              | 1,100              |            | 901               |            | 1,014          |            | 976               |            | 999               |            | 1,064              |            |
| Median                            | 1,183              |            | 858               |            | 995            |            | 944               |            | 960               |            | 1,063              |            |
| SD                                | 482.2              |            | 520.4             |            | 515.3          |            | 505.3             |            | 497.3             |            | 511.3              |            |
| Min                               | 7                  |            | 1                 |            | 1              |            | 12                |            | 85                |            | 3                  |            |
| Max                               | 1,894              |            | 1,898             |            | 1,898          |            | 1,898             |            | 1,898             |            | 1,898              |            |

<sup>a</sup> Follow-up time is calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**Table 4. ILD Broad Definition Study Population Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            | <b>Dofetilide</b> |            | <b>Propafenone</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|-------------------|------------|--------------------|------------|
| <b>Episode length<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>           | <b>%</b>   |
| <b>All Patients</b>               | <b>6,947</b>       | <b>100</b> | <b>11,625</b>     | <b>100</b> | <b>5,083</b>   | <b>100</b> | <b>4,469</b>      | <b>100</b> | <b>663</b>        | <b>100</b> | <b>2,763</b>       | <b>100</b> |
| 1-90 days                         | 2,023              | 29.1       | 4,335             | 37.3       | 1,249          | 24.6       | 1,588             | 35.5       | 111               | 16.7       | 1,169              | 42.3       |
| 91-180 days                       | 1,326              | 19.1       | 3,012             | 25.9       | 821            | 16.2       | 717               | 16.0       | 95                | 14.3       | 435                | 15.7       |
| 181-365 days                      | 1,305              | 18.8       | 2,254             | 19.4       | 1,006          | 19.8       | 832               | 18.6       | 146               | 22.0       | 427                | 15.5       |
| 366-545 days                      | 765                | 11.0       | 972               | 8.4        | 700            | 13.8       | 459               | 10.3       | 92                | 13.9       | 226                | 8.2        |
| 546-730 days                      | 502                | 7.2        | 431               | 3.7        | 417            | 8.2        | 269               | 6.0        | 77                | 11.6       | 149                | 5.4        |
| >730 days                         | 1,026              | 14.8       | 621               | 5.3        | 890            | 17.5       | 604               | 13.5       | 142               | 21.4       | 357                | 12.9       |
| Mean                              | 346                |            | 221               |            | 396            |            | 321               |            | 453               |            | 302                |            |
| Median                            | 193                |            | 120               |            | 250            |            | 165               |            | 337               |            | 119                |            |
| SD                                | 372.0              |            | 251.5             |            | 395.2          |            | 368.3             |            | 390.0             |            | 388.3              |            |
| Min                               | 1                  |            | 1                 |            | 1              |            | 1                 |            | 1                 |            | 1                  |            |
| Max                               | 1,886              |            | 1,890             |            | 1,893          |            | 1,898             |            | 1,853             |            | 1,889              |            |

<sup>a</sup> Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.



**Table 5. ILD Broad Definition Study Population Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                                           | Dronedarone |      | Amiodarone |      | Sotalol |      | Flecainide |      | Dofetilide |      | Propafenone |      |
|-----------------------------------------------------------|-------------|------|------------|------|---------|------|------------|------|------------|------|-------------|------|
| Drug Treatment Episodes                                   | N           | %    | N          | %    | N       | %    | N          | %    | N          | %    | N           | %    |
| All Patients                                              | 6,947       | 100  | 11,625     | 100  | 5,083   | 100  | 4,469      | 100  | 663        | 100  | 2,763       | 100  |
| Index Drug Treatment Episodes                             |             |      |            |      |         |      |            |      |            |      |             |      |
| 1                                                         | 4,743       | 68.3 | 7,097      | 61.0 | 3,164   | 62.2 | 2,769      | 62.0 | 438        | 66.1 | 1,844       | 66.7 |
| 2                                                         | 1,253       | 18.0 | 2,365      | 20.3 | 1,005   | 19.8 | 879        | 19.7 | 138        | 20.8 | 462         | 16.7 |
| 3                                                         | 512         | 7.4  | 1,068      | 9.2  | 455     | 9.0  | 407        | 9.1  | 47         | 7.1  | 235         | 8.5  |
| 4+                                                        | 439         | 6.3  | 1,095      | 9.4  | 459     | 9.0  | 414        | 9.3  | 40         | 6.0  | 222         | 8.0  |
| Mean                                                      | 1.6         |      | 1.8        |      | 1.8     |      | 1.8        |      | 1.6        |      | 1.7         |      |
| Median                                                    | 1           |      | 1          |      | 1       |      | 1          |      | 1          |      | 1           |      |
| SD                                                        | 1.2         |      | 1.3        |      | 1.4     |      | 1.4        |      | 1.1        |      | 1.3         |      |
| Min                                                       | 1           |      | 1          |      | 1       |      | 1          |      | 1          |      | 1           |      |
| Max                                                       | 14          |      | 12         |      | 19      |      | 17         |      | 10         |      | 16          |      |
| Number of Non-Index Study Drugs Dispensed Post Index Date |             |      |            |      |         |      |            |      |            |      |             |      |
| 0                                                         | 4,574       | 65.8 | 10,104     | 86.9 | 3,793   | 74.6 | 3,425      | 76.6 | 528        | 79.6 | 1,838       | 66.5 |
| 1                                                         | 1,917       | 27.6 | 1,277      | 11.0 | 1,018   | 20.0 | 782        | 17.5 | 114        | 17.2 | 702         | 25.4 |
| 2                                                         | 385         | 5.5  | 211        | 1.8  | 233     | 4.6  | 213        | 4.8  | 19         | 2.9  | 195         | 7.1  |
| 3                                                         | 63          | 0.9  | 28         | 0.2  | 35      | 0.7  | 45         | 1.0  | 2          | 0.3  | 25          | 0.9  |
| 4                                                         | 8           | 0.12 | 5          | 0.04 | 4       | 0.08 | 4          | 0.09 | 0          | 0.0  | 3           | 0.11 |

## Characteristics of Patients in the ILD Broad Definition PS-matched Analysis Dataset

Three cohorts met the minimum required number of cases for retention as comparators in the PS-matched *ILD broad definition analysis dataset*. Those were the amiodarone, sotalol and flecainide cohorts. There were 3,594 patients per matched cohort (total 14,376 patients).

**Table 6** provides a comparison of patient characteristics for the overall *ILD Broad definition study population* to those of the corresponding analysis dataset. Standardized differences are included for comparisons of each characteristic, by comparator cohort, to the corresponding value for the dronedarone cohort. Values exceeding 25 are considered to represent a significant difference in each paired comparison. Baseline demographic characteristics and selected baseline disease and medication use history for the PS-matched cohorts are summarized in **Table 7**.

**Table 6. Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Broad Definition Population vs. ILD Broad Definition Analysis Dataset: DoD Database - 20 July 2009 to 30 September 2014**

|                                         | Prior to PS Matching |       |       |       |                       |      |      | PS-Matched Subsets |       |       |       |                       |      |      |
|-----------------------------------------|----------------------|-------|-------|-------|-----------------------|------|------|--------------------|-------|-------|-------|-----------------------|------|------|
|                                         | Mean Value or %      |       |       |       | 100*Difference/<br>SD |      |      | Mean Value or %    |       |       |       | 100*Difference/<br>SD |      |      |
| Covariates                              | MQ                   | AM    | SO    | FL    | AM                    | SO   | FL   | MQ                 | AM    | SO    | FL    | AM                    | SO   | FL   |
| Gender (% female)                       | 45.7%                | 41.3% | 46.2% | 48.5% | 8.9                   | 0.9  | 5.6  | 48.4%              | 48.2% | 46.7% | 49.2% | 0.6                   | 3.4  | 1.5  |
| Age on index date (mean)                | 69.3                 | 73.4  | 70.1  | 63.2  | 41.9                  | 7.9  | 51.2 | 67.2               | 69    | 69.7  | 66.7  | 16.9                  | 23.7 | 5.2  |
| Study year of index date (mean)         | 2.6                  | 2.9   | 2.8   | 3     | 26.2                  | 19.5 | 33.7 | 2.9                | 2.6   | 2.7   | 2.9   | 23.4                  | 19.6 | 4.0  |
| Toxin exposure-Y/N                      | 0.1%                 | 0.2%  | 0.1%  | 0.2%  | 0.9                   | 0.7  | 0.9  | 0.1%               | 0.1%  | 0.1%  | 0.2%  | 1.9                   | 2.7  | 4.5  |
| Asthma-Y/N                              | 9.1%                 | 8.3%  | 8.4%  | 9.3%  | 2.6                   | 2.4  | 0.8  | 8.7%               | 8.8%  | 8.5%  | 9.5%  | 0.7                   | 0.5  | 2.8  |
| COPD-Y/N                                | 14.2%                | 18.5% | 13.8% | 7.2%  | 11.3                  | 1.1  | 22.3 | 11.7%              | 14.7% | 13.0% | 8.1%  | 8.9                   | 3.7  | 12.2 |
| Bronchitis-Y/N                          | 8.0%                 | 9.2%  | 8.1%  | 5.9%  | 4.5                   | 0.7  | 8.0  | 6.9%               | 7.1%  | 8.0%  | 6.4%  | 0.9                   | 4.2  | 2.1  |
| Therapeutic Oxygen-Y/N                  | 0.0%                 | 0.0%  | 0.0%  | 0.0%  | 2.4                   | 1.3  | 2.7  | 0.0%               | 0.0%  | 0.0%  | 0.0%  | 2.4                   | 2.4  | .    |
| Gastroesophageal Reflux-Y/N             | 27.0%                | 26.2% | 29.5% | 25.2% | 1.9                   | 5.5  | 4.2  | 27.3%              | 27.9% | 28.8% | 26.5% | 1.2                   | 3.3  | 1.8  |
| Connective Tissue Disease-Y/N           | 3.3%                 | 3.6%  | 3.6%  | 3.4%  | 1.6                   | 2.0  | 0.5  | 3.1%               | 3.8%  | 3.6%  | 4.0%  | 3.7                   | 2.9  | 4.7  |
| Hospitalized-Y/N                        | 44.6%                | 64.7% | 60.8% | 35.9% | 41.5                  | 32.9 | 17.7 | 40.2%              | 42.2% | 49.1% | 38.0% | 4.0                   | 17.9 | 4.5  |
| Potentially ILD inducing medication-Y/N | 92.4%                | 94.7% | 89.9% | 87.1% | 9.5                   | 8.9  | 18.1 | 90.4%              | 92.7% | 91.6% | 90.3% | 8.2                   | 4.1  | 0.2  |
| Pulmonology specialty visits-Y/N        | 11.1%                | 12.4% | 9.6%  | 9.3%  | 4.1                   | 4.9  | 5.8  | 9.7%               | 12.1% | 9.3%  | 9.2%  | 7.7                   | 1.5  | 1.9  |
| Other study drug-Y/N                    | 2.8%                 | 0.6%  | 0.9%  | 0.6%  | 19.1                  | 13.9 | 15.9 | 0.5%               | 1.6%  | 1.2%  | 0.8%  | 10.8                  | 7    | 3.1  |
| Other anti-arrhythmic therapy-Y/N       | 0.5%                 | 0.5%  | 0.4%  | 0.4%  | 0.1                   | 2.8  | 2.8  | 0.4%               | 0.6%  | 0.4%  | 0.4%  | 2.0                   | 0.0  | 0.4  |
| Number of office visits (mean)          | 12.2                 | 11.6  | 11.4  | 10.8  | 6.7                   | 9.0  | 15.8 | 10.8               | 12    | 11.8  | 11.4  | 13.5                  | 11.8 | 6.6  |
| Visited ER-Y/N                          | 51.5%                | 56.2% | 55.5% | 53.6% | 9.3                   | 7.9  | 4.1  | 50.1%              | 49.0% | 51.8% | 52.8% | 2.2                   | 3.5  | 5.5  |
| Number of different medications (mean)  | 10.9                 | 11.8  | 10.7  | 9     | 15.8                  | 3.1  | 35.3 | 9.8                | 10.8  | 10.7  | 9.6   | 18.4                  | 16.9 | 3.2  |

Abbreviations MQ=Dronedarone, AM-Amiodarone, SO=Sotalol, FL=Flecainide

**Table 7. Baseline Characteristics of Patients in the ILD Broad Definition Analysis Dataset according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                        | Dronedarone  |            | Amiodarone   |            | Sotalol      |            | Flecainide   |            |
|----------------------------------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
| Characteristics, N %                   | N            | %          | N            | %          | N            | %          | N            | %          |
| <b>All Patients</b>                    | <b>3,594</b> | <b>100</b> | <b>3,594</b> | <b>100</b> | <b>3,594</b> | <b>100</b> | <b>3,594</b> | <b>100</b> |
| <b>Demographics</b>                    |              |            |              |            |              |            |              |            |
| Age at cohort entry date, Mean(SD)     | 67.2         | 10.2       | 69.0         | 10.4       | 69.7         | 10.2       | 66.7         | 11.1       |
| 18-39 years                            | 37           | 1.0        | 43           | 1.2        | 44           | 1.2        | 81           | 2.3        |
| 40-49 years                            | 153          | 4.3        | 98           | 2.7        | 96           | 2.7        | 189          | 5.3        |
| 50-59 years                            | 516          | 14.4       | 444          | 12.4       | 336          | 9.3        | 498          | 13.9       |
| 60-69 years                            | 1,346        | 37.5       | 1,181        | 32.9       | 1,170        | 32.6       | 1,309        | 36.4       |
| 70-79 years                            | 1,160        | 32.3       | 1,263        | 35.1       | 1,344        | 37.4       | 1,106        | 30.8       |
| 80+ years                              | 382          | 10.6       | 565          | 15.7       | 604          | 16.8       | 411          | 11.4       |
| Gender(female)                         | 1,741        | 48.4       | 1,731        | 48.2       | 1,680        | 46.7       | 1,768        | 49.2       |
| Race                                   |              |            |              |            |              |            |              |            |
| White                                  | 1,410        | 39.2       | 1,175        | 32.7       | 1,163        | 32.4       | 1,384        | 38.5       |
| Asian or Pacific Islander              | 42           | 1.2        | 52           | 1.4        | 29           | 0.8        | 46           | 1.3        |
| Black                                  | 101          | 2.8        | 128          | 3.6        | 79           | 2.2        | 113          | 3.1        |
| American Indian/Alaskan Native         | 7            | 0.2        | 6            | 0.2        | 7            | 0.2        | 6            | 0.2        |
| Two races reported                     | 16           | 0.4        | 12           | 0.3        | 15           | 0.4        | 24           | 0.7        |
| Other                                  | 46           | 1.3        | 39           | 1.1        | 31           | 0.9        | 44           | 1.2        |
| Unknown                                | 1,972        | 54.9       | 2,182        | 60.7       | 2,270        | 63.2       | 1,977        | 55.0       |
| <b>History of Disease</b>              |              |            |              |            |              |            |              |            |
| Deyo-Charlson Index, Mean(SD)          | 1.0          | 1.4        | 1.5          | 1.7        | 1.2          | 1.4        | 0.9          | 1.2        |
| Asthma                                 | 311          | 8.7        | 318          | 8.8        | 306          | 8.5        | 340          | 9.5        |
| Bronchitis                             | 248          | 6.9        | 256          | 7.1        | 288          | 8.0        | 229          | 6.4        |
| Chronic Obstructive Pulmonary Disease  | 422          | 11.7       | 530          | 14.7       | 466          | 13.0       | 291          | 8.1        |
| Connective Tissue Disease              | 111          | 3.1        | 135          | 3.8        | 130          | 3.6        | 142          | 4.0        |
| Exposure to Toxins                     | 2            | 0.1        | 4            | 0.1        | 5            | 0.1        | 8            | 0.2        |
| Gastroesophageal Reflux Disease        | 981          | 27.3       | 1,001        | 27.9       | 1,034        | 28.8       | 952          | 26.5       |
| <b>History of Medication Use</b>       |              |            |              |            |              |            |              |            |
| Other Anti-arrhythmic Agents           | 15           | 0.4        | 20           | 0.6        | 15           | 0.4        | 14           | 0.4        |
| Agents assoc w drug-induced pulmon dis | 3,249        | 90.4       | 3,331        | 92.7       | 3,291        | 91.6       | 3,247        | 90.3       |
| Therapeutic Oxygen Treatment           | 0            | 0.0        | 1            | 0.03       | 1            | 0.03       | 0            | 0.0        |

### **Baseline Characteristics**

As seen in [Table 6](#), prior to PS matching there were four patient characteristics with at least one comparison that differed significantly from the corresponding measure in the dronedarone cohort. Those characteristics were mean age on index date, mean study year of index date, hospitalization in the baseline and mean number of different medications in the baseline. All other variables were considered balanced across cohorts in the overall study population. The table also shows that the PS-matched analysis dataset was well balanced on all variables (i.e., no standardized differences of 25 or greater).

The range of mean age changed from a ten-year span of 63.2 – 73.4 prior to matching, to the smaller interval of 66.7-69.7 in the matched data. Mean age in the analysis dataset is lower than in the overall study population in all cohorts except flecainide, where it was higher by 3.5 years. ([Table 5 and Table 6](#)) Significant imbalances between mean age of the dronedarone cohort compared to the amiodarone and flecainide cohorts prior to PS matching were eliminated in the matched dataset.

Similarly, significant differences in mean study year of patient index date between the dronedarone cohort and both amiodarone and flecainide cohorts were found in the overall study population. In the PS-matched analysis dataset, however, the mean year of index date was more similar across all cohorts, and differences were not significant.

Percentages of the amiodarone and sotalol cohorts with at least one baseline hospitalization were significantly higher than the corresponding percentage of the dronedarone cohort in the overall study population, but those differences were also balanced in the PS-matched data.

The last significant difference in the overall study population was between the dronedarone and flecainide cohorts with regard to average number of different medications dispensed in the baseline. That comparison showed a significantly lower mean number of different drugs dispensed to the flecainide group prior to their index date (9.0 vs 10.9 in the dronedarone cohort, standardized difference=35.3). PS-matching also brought that variable into balance across all cohorts.

Distributions of patients by demographic characteristics and history of medication use in the *ILD Broad definition analysis dataset* varied little from the corresponding values in the *ILD Narrow definition analysis dataset*. Mean age on index date (range of roughly 66.7 to 69.7) and percent female (range 46.7% to 49.2%) were roughly the same across the *ILD Broad definition* cohorts. Approximately 90% of patients in each cohort had been dispensed at least one drug suspected of being associated with pulmonary disease, and less than one percent of each group had used other anti-arrhythmic agents in the baseline period.

In general, similar but slightly lower proportions of patients in the *ILD Broad definition analysis dataset* had diagnoses for the specific conditions itemized in [Table 7](#), versus the *ILD*

*Narrow definition analysis dataset.* Mean DCI was slightly lower in the *ILD Broad definition analysis dataset* than in the *ILD Narrow definition analysis dataset* for all but the flecainide cohort (range 0.9-1.5). In most cases, lower proportions of patients in the PS-matched broad definition analysis dataset had baseline diagnoses of asthma, bronchitis, COPD, connective tissue disease and exposure to toxins. The somewhat lower mean DCI and proportions of patients with the specified diagnoses may be a result of additional patients eliminated from the *ILD Broad definition study population* by the added screening criteria (i.e., broader list of baseline diagnoses).

### **Post-Index Date characteristics**

#### **Patient Follow-Up Time**

Follow-up time for patients in the *ILD broad definition analysis dataset* is summarized in **Table 8**. Mean follow-up time ranged from 994 days (33.1 months) in the dronedarone cohort to 1,066 days (35.5 months) in the sotalol cohort. Length of follow-up exceeded 730 days (roughly 2 years) for two-thirds or more of patients in all cohorts (range 64.6% -70.5%).

**Table 8. ILD Broad Definition Analysis Dataset Follow-up Time according to Study Drug Cohort: DoD Database - 20 July 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|
| <b>Follow-up Time<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   |
| <b>All Patients</b>               | <b>3,594</b>       | <b>100</b> | <b>3,594</b>      | <b>100</b> | <b>3,594</b>   | <b>100</b> | <b>3,594</b>      | <b>100</b> |
| 1-90 days                         | 23                 | 0.6        | 73                | 2.0        | 36             | 1.0        | 14                | 0.4        |
| 91-180 days                       | 11                 | 0.3        | 56                | 1.6        | 32             | 0.9        | 17                | 0.5        |
| 181-365 days                      | 418                | 11.6       | 363               | 10.1       | 341            | 9.5        | 405               | 11.3       |
| 366-545 days                      | 410                | 11.4       | 313               | 8.7        | 317            | 8.8        | 365               | 10.2       |
| 546-730 days                      | 411                | 11.4       | 314               | 8.7        | 336            | 9.3        | 370               | 10.3       |
| >730 days                         | 2,321              | 64.6       | 2,475             | 68.9       | 2,532          | 70.5       | 2,423             | 67.4       |
| Mean                              | 994                |            | 1,031             |            | 1,066          |            | 1,026             |            |
| Median                            | 999                |            | 1,072             |            | 1,104          |            | 1,023             |            |
| SD                                | 493.9              |            | 510.3             |            | 504.7          |            | 500.9             |            |
| Min                               | 12                 |            | 1                 |            | 11             |            | 12                |            |
| Max                               | 1,889              |            | 1,898             |            | 1,898          |            | 1,898             |            |

<sup>a</sup>Follow-up time is calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

#### **Length of Index Treatment Episode**

Data on length of index treatment episodes for patients in the *ILD broad definition analysis dataset* are reported in **Table 9**. Variations across cohorts observed in the overall *ILD Broad definition study population* remained in the PS-matched analysis dataset. The mean index

treatment episode length ranged from 225 days (7.5 months) in the amiodarone cohort to 399 days (13.3 months) in the sotalol cohort.

**Table 9. ILD Broad Definition Analysis Dataset Length of Index Treatment Episode according to Study Drug Cohort: DoD Database - July 20, 2009 through 30 September 2014**

|                                   | <b>Dronedarone</b> |            | <b>Amiodarone</b> |            | <b>Sotalol</b> |            | <b>Flecainide</b> |            |
|-----------------------------------|--------------------|------------|-------------------|------------|----------------|------------|-------------------|------------|
| <b>Episode Length<sup>a</sup></b> | <b>N</b>           | <b>%</b>   | <b>N</b>          | <b>%</b>   | <b>N</b>       | <b>%</b>   | <b>N</b>          | <b>%</b>   |
| <b>All Patients</b>               | <b>3,594</b>       | <b>100</b> | <b>3,594</b>      | <b>100</b> | <b>3,594</b>   | <b>100</b> | <b>3,594</b>      | <b>100</b> |
| 1-90 days                         | 1,066              | 29.7       | 1,309             | 36.4       | 895            | 24.9       | 1,197             | 33.3       |
| 91-180 days                       | 688                | 19.1       | 986               | 27.4       | 591            | 16.4       | 549               | 15.3       |
| 181-365 days                      | 731                | 20.3       | 661               | 18.4       | 695            | 19.3       | 672               | 18.7       |
| 366-545 days                      | 395                | 11.0       | 288               | 8.0        | 474            | 13.2       | 381               | 10.6       |
| 546-730 days                      | 260                | 7.2        | 137               | 3.8        | 279            | 7.8        | 235               | 6.5        |
| >730 days                         | 454                | 12.6       | 213               | 5.9        | 660            | 18.4       | 560               | 15.6       |
| Mean                              | 325                |            | 225               |            | 399            |            | 348               |            |
| Median                            | 190                |            | 119               |            | 246            |            | 192               |            |
| SD                                | 348.4              |            | 261.8             |            | 400.5          |            | 388.8             |            |
| Min                               | 1                  |            | 1                 |            | 1              |            | 1                 |            |
| Max                               | 1,886              |            | 1,890             |            | 1,867          |            | 1,898             |            |

<sup>a</sup>Length of index treatment episode is calculated as time from Index Date to the end of the index treatment episode.

## D. SENSITIVITY ANALYSES RESULTS

### SENSITIVITY ANALYSES PARAMETERS

**Table 10** lists the combinations of ILD definition, analysis dataset, and risk periods used for the primary ILD analysis and each of the ILD sensitivity analyses.

**Table 10. ILD Analyses Study Cohort and Risk Period Combinations**

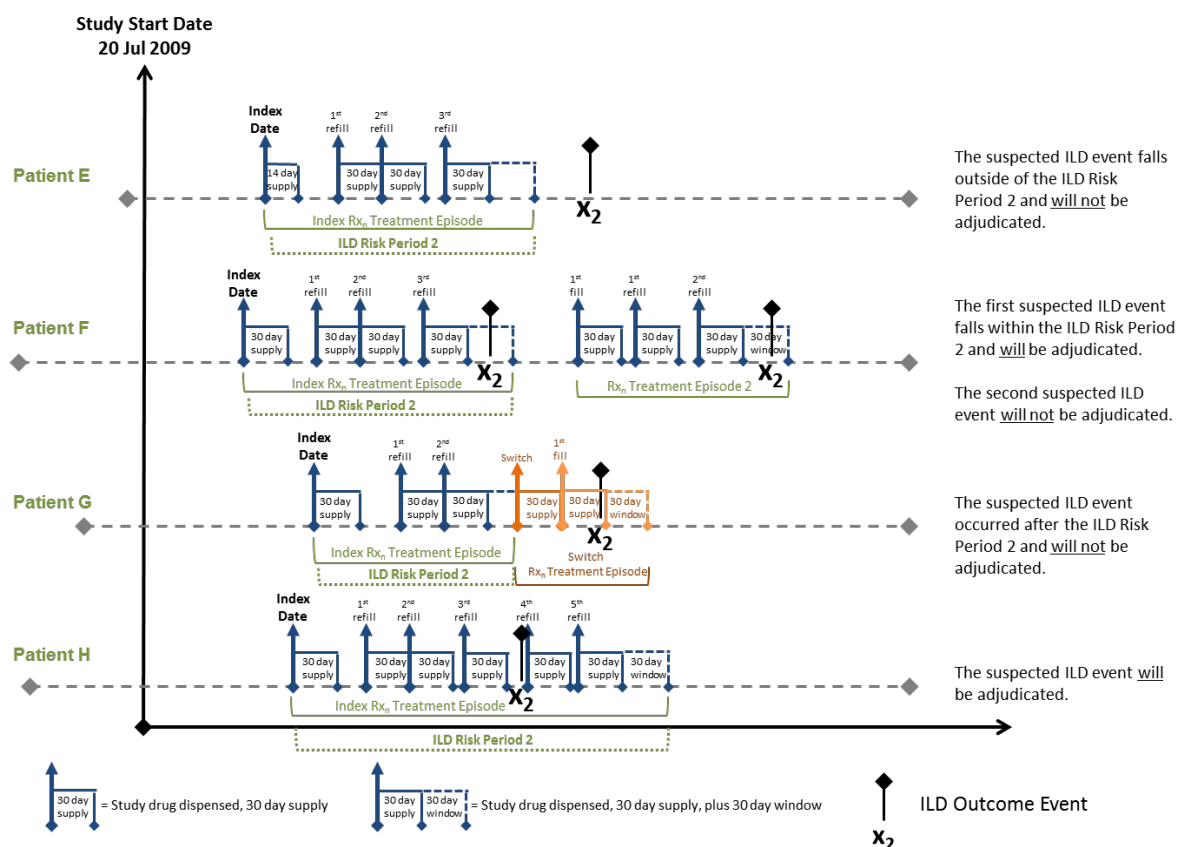
| Analysis               | ILD Definition | Analysis Dataset             | Risk Period       |
|------------------------|----------------|------------------------------|-------------------|
| Primary analysis       | Narrow         | <i>ILD Narrow definition</i> | ILD Risk Period 1 |
| Sensitivity analysis 1 | Narrow         | <i>ILD Narrow definition</i> | ILD Risk Period 2 |
| Sensitivity analysis 2 | Broad          | <i>ILD Broad definition</i>  | ILD Risk Period 1 |
| Sensitivity analysis 3 | Broad          | <i>ILD Broad definition</i>  | ILD Risk Period 2 |

**ILD Risk Period 1** was the period that began the day after the Index Date and continued until the earliest occurrence of an ILD outcome, the end of MHS eligibility, death, or the end of follow-up (see [Appendix 7 – Figure 2](#)).

**ILD Risk Period 2** has a shorter maximum observation period. Beginning the day after the Index Date, **ILD Risk Period 2** ended at the earliest occurrence of an ILD outcome, the end of MHS eligibility, death, or the end of the index treatment episode (see [Figure 1](#)).



**Figure 1. Suspected ILD Outcome Event Identification during ILD Risk Period 2**



## ILD Sensitivity Analysis 1

*Sensitivity Analysis 1* was conducted in the *ILD Narrow definition analysis dataset*, using the same narrow definition of ILD as the primary analysis to identify suspected outcomes. This sensitivity analysis varied from the ILD primary analysis by limiting suspected ILD outcomes to those identified during *Risk Period 2*. Characteristics of patients included in the *ILD Narrow definition study population* and *ILD Narrow definition analysis dataset* are described in [Section 9.2](#) of this report.

### *ILD Sensitivity Analysis 1 Adjudication Results*

A total 33 cases of suspected narrow definition ILD were identified in the interval from index date through end of index treatment episode. ([Table 11](#)) The ILD-AP confirmed eleven of those cases as true ILD outcome events (i.e., adjudication result="Yes"). Most of the confirmed cases occurred in the amiodarone cohort (n=8), two were in the dronedarone cohort and one in the flecainide cohort. None of the seven suspected cases in the sotalol cohort were confirmed by the ILD-AP. Of the remaining 22 suspected cases, seventeen were adjudicated as "No", and the remaining five received an assessment of "Indeterminate" (i.e., insufficient evidence to make a definitive conclusion).

**Table 11. Adjudication Results of Suspected ILD Narrow Definition Outcome Events within the Index Treatment Episode according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                            | Dronedarone<br>N=4,087 |      | Amiodarone<br>N=4,087 |      | Sotalol<br>N=4,087 |      | Flecainide<br>N=4,087 |      |
|--------------------------------------------|------------------------|------|-----------------------|------|--------------------|------|-----------------------|------|
| Characteristics, N %                       | N                      | %    | N                     | %    | N                  | %    | N                     | %    |
| All Patients with Suspected Outcome Events | 5                      | 100  | 17                    | 100  | 7                  | 100  | 4                     | 100  |
| <b>Adjudication Determination</b>          |                        |      |                       |      |                    |      |                       |      |
| Yes                                        | 2                      | 40.0 | 8                     | 47.1 | 0                  | 0.0  | 1                     | 25.0 |
| No                                         | 3                      | 60.0 | 8                     | 47.1 | 4                  | 57.1 | 2                     | 50.0 |
| Indeterminate                              | 0                      | 0.0  | 1                     | 5.9  | 3                  | 42.9 | 1                     | 25.0 |

### *ILD Sensitivity Analysis 1 Main Results*

[Table 12](#) reports incidence rates and hazard ratios for the confirmed cases of narrow definition ILD identified during patients' index treatment episodes. Reported p values are for each individual comparator cohort versus the dronedarone cohort. While the specific rates differ from those of the primary ILD narrow definition analysis, contrasting rates in the comparator cohorts to corresponding values in the dronedarone cohort yield essentially the same findings.

The incidence rate of narrow definition ILD during the index treatment episode was significantly higher in the amiodarone cohort than in the dronedarone cohort (3.2 per 1,000 persons years of exposure versus 0.6 per 1,000 person years of exposure; p=0.02). The

incidence rates in the flecainide cohort (0.3 per 1,000 person years of exposure) did not differ notably from the rate in the dronedarone cohort.

Similarly, CPH analysis identified a significant excess risk of narrow definition ILD over the course of the index treatment episode for patients in the amiodarone cohort, as compared to the dronedarone cohort (HR=5.2; 95% CI=1.1-25.1). The hazard ratio comparing the same risk for the flecainide versus dronedarone cohorts were not significant.

**Table 12. ILD Narrow Definition Analysis Dataset Incidence Rates (per 1,000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during the Index Treatment Episode: DOD Database - 20 July 2009 to 30 September 2014**

|                                           | <b>Dronedarone<br/>N=4,087</b> | <b>Amiodarone<br/>N=4,087</b> | <b>Sotalol<br/>N=4,087</b> | <b>Flecainide<br/>N=4,087</b> |
|-------------------------------------------|--------------------------------|-------------------------------|----------------------------|-------------------------------|
| <b>Cases adjudicated as Yes</b>           |                                |                               |                            |                               |
| Cases during exposure period <sup>a</sup> | 2                              | 8                             | 0                          | 1                             |
| Person-Years of exposure <sup>b</sup>     | 3,541.3                        | 2,471.4                       | 4,445.1                    | 3,832.2                       |
| Incidence rate (95% CI)                   | 0.6 (0.1-2.0)                  | 3.2 (1.4-6.4)                 | nc                         | 0.3 (0.0-1.5)                 |
| p-value IR difference from Dronedarone    | --                             | 0.02                          |                            | 0.57                          |
| Hazard Ratio (95%CI) <sup>c</sup>         | Reference                      | 5.2 (1.1-25.1)                | nc                         | 0.5 (0.0-5.6)                 |
| p-value of Hazard Ratio                   | --                             | 0.04                          | 1                          | 0.58                          |

nc = value cannot be calculated

<sup>a</sup> The exposure period (ILD Risk Period 2) begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>b</sup> Person years of exposure is the sum of total days in ILD Risk Period 2 for all patients in the ILD Narrow definition analysis dataset.

<sup>c</sup> Hazard ratio for dronedarone-flecainide comparison is a crude rate. Hazard ratio for dronedarone-amiodarone comparison is adjusted for study year of index date. Hazard ratio for dronedarone-sotalol comparison is adjusted for age on index date.

## ILD Sensitivity Analysis 2

### *ILD Sensitivity Analysis 2 Adjudication Results*

A total of 122 suspected cases of broad definition ILD were identified in the *ILD Broad definition analysis dataset*, and the adjudication process confirmed 45 of those as true ILD outcome events (i.e., adjudication result="Yes"). Most of the cases not confirmed to be ILD were adjudicated as "No" (n=69), and the remaining eight were adjudicated as "Indeterminate" (i.e., there was not enough information to reach a definitive conclusion).

The largest single number of confirmed cases of Broad definition ILD during Risk period 1 (i.e., through the end of the follow-up period) occurred in the amiodarone cohort (16 cases). That was twice the number of cases as occurred in the dronedarone cohort. The flecainide and sotalol cohorts had 10 and 11 confirmed cases, respectively. See [Table 13](#).

Although a net of eight more suspected cases of ILD were identified during the follow-up period using the broad versus narrow definitions of ILD to screen patients and identify

outcomes (n=122 versus n=113), the number of confirmed cases was higher in the analysis using the broad definition.

**Table 13. Adjudication Results of Suspected ILD Broad Definition Outcome Events within the Follow-up according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                            | Dronedarone<br>N=3,594 |      | Amiodarone<br>N=3,594 |      | Sotalol<br>N=3,594 |      | Flecainide<br>N=3,594 |      |
|--------------------------------------------|------------------------|------|-----------------------|------|--------------------|------|-----------------------|------|
| Characteristics, N %                       | N                      | %    | N                     | %    | N                  | %    | N                     | %    |
| All Patients with Suspected Outcome Events | 26                     | 100  | 38                    | 100  | 35                 | 100  | 23                    | 100  |
| <b>Adjudication Determination</b>          |                        |      |                       |      |                    |      |                       |      |
| Yes                                        | 8                      | 30.8 | 16                    | 42.1 | 11                 | 31.4 | 10                    | 43.5 |
| No                                         | 16                     | 61.5 | 20                    | 52.6 | 21                 | 60.0 | 12                    | 52.2 |
| Indeterminate                              | 2                      | 7.7  | 2                     | 5.3  | 3                  | 8.6  | 1                     | 4.3  |

### **ILD Sensitivity Analysis 2 Main Results**

Incidence of confirmed broad definition ILD during the follow-up period ranged from 0.8 per 1,000 person years of follow-up in the dronedarone cohort to 1.6 per 1,000 person years of follow-up in the amiodarone cohort. (See [Table 14](#)) Notwithstanding the amiodarone rate being double that of the dronedarone cohort, none of the differences in incidence rates between the dronedarone cohort and any of the three comparator cohorts were significant.

Similarly, none of the hazard ratios comparing risk of broad definition ILD over the course of the follow-up period between each of the comparator cohorts and the dronedarone cohort were significant.

**Table 14. ILD Broad Definition Analysis Dataset Incidence Rates (per 1,000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during Follow-up Period: DOD Database - 20 July 2009 to 30 September 2014**

|                                           | Dronedarone<br>N=3,594 | Amiodarone<br>N=3,594 | Sotalol<br>N=3,594 | Flecainide<br>N=3,594 |
|-------------------------------------------|------------------------|-----------------------|--------------------|-----------------------|
| <b>Cases adjudicated as Yes</b>           |                        |                       |                    |                       |
| Cases during exposure period <sup>a</sup> | 8                      | 16                    | 11                 | 10                    |
| Person-Years of exposure <sup>b</sup>     | 9,777.4                | 10,126.5              | 10,483.4           | 10,089.5              |
| Incidence rate (95% CI)                   | 0.8 (0.4-1.6)          | 1.6 (0.9-2.6)         | 1.0 (0.5-1.9)      | 1.0 (0.5-1.8)         |
| p-value IR difference from Dronedarone    | --                     | 0.13                  | 0.65               | 0.69                  |
| Crude HR (95%CI)                          | Reference              | 1.9 (0.8-4.5)         | 1.2 (0.5-3.1)      | 1.2 (0.5-3.1)         |
| p-value of Hazard Ratio                   | --                     | 0.13                  | 0.65               | 0.69                  |

<sup>a</sup> The exposure period (ILD Risk Period 1) begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>b</sup> Person years of exposure is the sum of total days in ILD Risk Period 1 for all patients in the ILD Broad definition analysis dataset.

## ILD Sensitivity Analysis 3

### *ILD Sensitivity Analysis 3 Adjudication Results*

Numbers of suspected ILD broad definition outcome events identified through the end of the index treatment episode, and their adjudication results, are found in [Table 15](#). A total of 33 cases with a broad definition ILD diagnosis that could potentially be attributed to drug treatment were identified.

Less than one third of the suspected cases (9 cases) in this sensitivity analysis were confirmed as true ILD outcome events. Most of the confirmed cases were in the amiodarone cohort (6 cases), and the remaining three were distributed one each in the dronedarone, sotalol and flecainide cases. The bulk of the suspected outcomes (20 cases) were adjudicated as “No.” No definite conclusion could be reached about the remaining four cases.

**Table 15. Adjudication Results of Suspected ILD Broad Definition Outcome Events within the Index Treatment Episode according to Study Drug Cohort: DOD Database - 20 July 2009 to 30 September 2014**

|                                            | <b>Dronedarone<br/>N=3,594</b> |          | <b>Amiodarone<br/>N=3,594</b> |          | <b>Sotalol<br/>N=3,594</b> |          | <b>Flecainide<br/>N=3,594</b> |          |
|--------------------------------------------|--------------------------------|----------|-------------------------------|----------|----------------------------|----------|-------------------------------|----------|
| <b>Characteristics, N %</b>                | <b>N</b>                       | <b>%</b> | <b>N</b>                      | <b>%</b> | <b>N</b>                   | <b>%</b> | <b>N</b>                      | <b>%</b> |
| All Patients with Suspected Outcome Events | 5                              | 100      | 12                            | 100      | 12                         | 100      | 4                             | 100      |
| <b>Adjudication Determination</b>          |                                |          |                               |          |                            |          |                               |          |
| Yes                                        | 1                              | 20.0     | 6                             | 50.0     | 1                          | 8.3      | 1                             | 25.0     |
| No                                         | 4                              | 80.0     | 5                             | 41.7     | 9                          | 75.0     | 2                             | 50.0     |
| Indeterminate                              | 0                              | 0.0      | 1                             | 8.3      | 2                          | 16.7     | 1                             | 25.0     |

### *ILD Sensitivity Analysis 3 Main Results*

[Table 16](#) displays incidence rates of confirmed cases of broad definition ILD identified through the end of the index treatment episode. The incidence rate for the amiodarone cohort was nine times that of the dronedarone, sotalol or flecainide cohorts (2.7 per 1,000 years of exposure in the amiodarone cohort versus 0.3 per 1,000 years of exposure for the dronedarone, sotalol and flecainide cohorts). The difference between the amiodarone and dronedarone incidence rates was significant ( $p=0.02$ ).

Also seen in [Table 16](#), the hazard of confirmed broad definition ILD during the index treatment episode was significantly higher for the amiodarone cohort versus the dronedarone cohort ( $HR=8.1$ ; 95%  $CI=1.0-67.7$ ,  $p=0.05$ ). The risk over the time of the index treatment episode was not significantly different for either the sotalol or flecainide cohorts as compared to the dronedarone cohort.

**Table 16. ILD Broad Definition Analysis Dataset Incidence Rates (per 1,000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during the Index Treatment Episode: DOD Database - 20 July 2009 to 30 September 2014**

|                                           | <b>Dronedarone<br/>N=3,594</b> | <b>Amiodarone<br/>N=3,594</b> | <b>Sotalol<br/>N=3,594</b> | <b>Flecainide<br/>N=3,594</b> |
|-------------------------------------------|--------------------------------|-------------------------------|----------------------------|-------------------------------|
| <b>Cases adjudicated as Yes</b>           |                                |                               |                            |                               |
| Cases during exposure period <sup>a</sup> | 1                              | 6                             | 1                          | 1                             |
| Person-Years of exposure <sup>b</sup>     | 3,199.7                        | 2,215.3                       | 3,923.7                    | 3,430.0                       |
| Incidence rate (95% CI)                   | 0.3 (0.0-1.7)                  | 2.7 (1.0-5.9)                 | 0.3 (0.0-1.4)              | 0.3 (0.0-1.6)                 |
| p-value IR difference from Dronedarone    | --                             | 0.02                          | 0.89                       | 0.99                          |
| Crude HR (95%CI)                          | Reference                      | 8.1 (1.0-67.7)                | 0.8 (0.1-13.2)             | 1.0 (0.1-16.4)                |
| p-value of Hazard Ratio                   | --                             | 0.05                          | 0.89                       | 0.99                          |

<sup>a</sup> The exposure period (ILD Risk Period 2) begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>b</sup> Person years of exposure is the sum of total days in ILD Risk Period 2 for all patients in the ILD Broad definition analysis dataset.





## **APPENDIX 14. DRONEDARONE EPIDEMIOLOGY STUDY PROTOCOL**



## **EPIDEMIOLOGY STUDY PROTOCOL**

### **SERIOUS LIVER INJURY AND INTERSTITIAL LUNG DISEASE OCCURRENCES IN PATIENTS DIAGNOSED WITH ATRIAL FIBRILLATION TREATED WITH SELECTED ANTI- ARRHYTHMICS**

**Study code: DRONE\_C\_05917**

---

Investigators/Authors:

Report type:

**Version 3.0**

**This study will be conducted in accordance with  
Sanofi standard operating procedures for epidemiologic studies**

---

**Date:** January 26, 2016

## STUDY SYNOPSIS

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**Drug name:** Dronedarone

---

**Title:** Serious Liver Injury and Interstitial Lung Disease Occurrences in Patients Diagnosed with Atrial Fibrillation Treated with Selected Anti-arrhythmics

---

**Background:** Post-marketing pharmacovigilance data of spontaneous reports indicated safety signals related to severe acute liver injury/disease (SLD), and interstitial lung disease (ILD). In order to examine these associations in the real-world setting, where dronedarone is approved for non-permanent AF, Sanofi requested a retrospective cohort study examining the association between dronedarone and selected anti-arrhythmic comparator drugs and these subsequent events among adults.

---

**Objective(s):** To compare rates of Serious Liver Injury/Disease and Interstitial Lung Disease, separately, in patients exposed to other selected anti-arrhythmic comparator cohorts versus dronedarone-exposed patients.

---

**Study design:** Observational retrospective cohort study

---

**Study Population:** Two healthcare data environments will be used for this study; the Department of Defense (DoD) electronic health record system and the HealthCore Integrated Research Database (HIRD<sup>SM</sup>), which is a healthcare payer claims database. Cohorts of new users of dronedarone, amiodarone, sotalol, flecainide, propafenone, and dofetilide will be selected from these data sources. Patient cohorts will be propensity score matched to patients in the dronedarone cohort to ensure balance in key variables among treatment groups. Separate analyses will be conducted in the two data environments.

All patients will be screened against an overall set of inclusion criteria. One set of event-specific exclusion criteria will be used to create the SLD study population. Two sets of event-specific exclusion criteria (narrow and broad) will be applied to create two ILD study populations. These two sets will attempt to address the various diagnosis codes used to identify ILD.

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|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Treatment Episodes:</b> | Treatment episodes will be identified for each study drug within the study period and will be defined as a continuous period starting on the date a study drug is dispensed, and continuing for the duration of the prescription's days' supply. In cases where there is a gap of fewer than 30 days between the date on which a prescription's days' supply ends, and the dispensing date of a subsequent prescription for the same drug, the subsequent prescription will be considered a continuation of the first treatment episode. The Index Treatment Episode will be the episode that begins on the patient's Index Date. |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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|                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Risk Periods</b> | <p>The SLD Risk Period is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the index treatment episode.</p> <p>The ILD risk period is defined in 2 ways. ILD Risk Period 1 is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the study period.</p> <p>ILD Risk Period 2 is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the index treatment episode.</p> |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

---

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Outcome(s) of interest:</b> | <p>The two primary outcome events of interest are hospitalized occurrences of:</p> <ol style="list-style-type: none"><li>1. Serious Liver Injury/Disease,</li><li>2. Interstitial Lung Disease.</li></ol> <p>A sensitivity analysis will also be conducted using a broader ILD definition for baseline exclusionary screening and suspected outcome event identification. Additionally, sensitivity analyses will be conducted in ILD Risk Period 2 using the same narrow and broader definitions that were used in ILD Risk Period 1. All suspected hospitalized outcome events will be adjudicated by their respective Independent Adjudication Panels.</p> |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**Covariates/ Confounders:** Should sufficient numbers of outcomes be identified for analysis, risk factors and potential confounders for serious liver injury/disease and interstitial lung disease will be identified. These variables will be identified in the eligibility files and notes as well as by diagnosis and procedure codes and drug files. If not included in cohort matching, these variables may be used for stratification or multivariable modeling in the statistical analysis.

**Confounders.** For SLD, potential risk factors / confounders include alcoholism, bile duct disorders, congestive heart failure, diabetes, obesity, prior use of anti-arrhythmic agents, and hepatotoxic medications. For ILD, potential risk factors / confounders include asthma, bronchitis, chronic obstructive pulmonary disease, connective tissue disorders, exposure to occupational and environmental toxins, gastroesophageal reflux disease, prior use of anti-arrhythmic agents, agents associated with pulmonary toxicity, and therapeutic oxygen treatment.

---

**Statistical Analysis:** **Power Calculation.** The number of dronedarone subjects required to provide 80% power, at the 0.05 alpha level, to detect a hazard ratio of 3.0 with 5 year accrual interval and an estimated incidence rate of 1 event / 1,000 patient-years, is 3,860 subjects with equal number of patients in the comparator group.

**Propensity score matching (PSM)** will utilize a nearest-neighbor-within-caliper matching algorithm.

**Analytic approach.** Descriptive summaries will be tabulated for each outcome event and for each exposure group: the number and proportion of subjects with and without the event, with 95% confidence intervals, and p-values, the number of patient-years of observation, the number of incident events, the unadjusted event rate with its 95% confidence interval, and p-value. Kaplan-Meier survival curves will be prepared and graphed, with one graph for each outcome, and a separate survival curve for each exposure group. The hazard function may be estimated from a life table, or from a fitted model of a survival curve, depending on the number of outcomes (SLD or ILD) observed in the exposure groups. Cox regression will be carried out for each outcome, and incorporating any other covariates of interest that were not included in the propensity score. Results will be presented as adjusted hazard ratios, with 95% confidence intervals and p values, for each comparator drug relative to dronedarone. A sensitivity analysis will be performed on the subset of the population that has available laboratory results/additional confounder data to test whether the additional data changes the effect estimates. Analyses will be run separately for each database, and the results of the analyses (hazard ratios, confidence intervals, p values, etc.) will be described.

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**Timeline:** See Study Timelines Section.

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## LIST OF ABBREVIATIONS

|                    |                                                                                           |
|--------------------|-------------------------------------------------------------------------------------------|
| AF                 | Atrial Fibrillation                                                                       |
| SLD                | Serious liver injury/disease                                                              |
| ILD                | Interstitial lung disease                                                                 |
| DoD                | US Department of Defense, Military Health System Database                                 |
| HIRD <sup>sm</sup> | HealthCore Integrated Research Database                                                   |
| Degge              | The Degge Group, Ltd.                                                                     |
| ESC                | Epidemiology Steering Committee                                                           |
| IAC                | Independent Adjudication Committee                                                        |
| HRTx               | Health ResearchTx, LLC                                                                    |
| EHR                | Electronic health record                                                                  |
| ICD-9-CM           | International Classification of Diseases, 9 <sup>th</sup> Revision, Clinical Modification |
| MHS                | Military Health System                                                                    |
| MTF                | Military Treatment Facility                                                               |
| CPT                | Current Procedural Terminology, American Medical Association                              |
| HCPCS              | Healthcare Common Procedure Coding System, Centers for Medicare & Medicaid Services       |
| NDC                | National Drug Code                                                                        |
| GPI                | Generic Product Indicator                                                                 |
| PSM                | Propensity score matching                                                                 |

## 1 INTRODUCTION

Dronedarone (Multaq®) is an anti-arrhythmic drug with effects in all four classes of the Vaughan Williams classification utilized for treatment of patients with non-permanent atrial fibrillation (AF).<sup>1\*</sup> Dronedarone was initially authorized for marketing on 1 July 2009 in the United States. It is currently marketed in 32 countries in the Americas, Europe, and Asia.

The goals of treatment for AF include ventricular rate control, anticoagulation for the prevention of thromboembolism, and *elective* conversion to normal sinus rhythm and maintenance of sinus rhythm, depending on the clinical state of the patient.<sup>2</sup> Initial treatment involves either ventricular rate control or rhythm control. If ventricular rate control is the initial treatment strategy, rhythm control is not considered a therapeutic objective. On the other hand, if rhythm control is the initial treatment strategy, concomitant management of rate control needs to be addressed. Regardless of initial treatment strategy, antithrombotic therapy should be considered. Response to initial therapy will guide further treatment decision-making.

Guidelines for the treatment of AF targeted rate and rhythm control (as well as anticoagulation) exist although some medications used for treatment are not indicated for AF.<sup>3,4</sup> Rate control therapy consists of treatment with beta-blockers, calcium channel blockers, and digoxin, while for rhythm control, amiodarone, and other anti-arrhythmic agents are used.

Post-marketing pharmacovigilance data of spontaneous reports associated with dronedarone indicate safety signals related to severe liver injury/disease (SLD), and interstitial lung disease (ILD). In order to examine these associations in the real-world setting, where dronedarone is approved for non-permanent AF, Sanofi requested a retrospective cohort study examining the association between dronedarone or comparator anti-arrhythmic drugs and these subsequent events among adults.

To accomplish this, data from the US Department of Defense (DoD) Military Health System (MHS) database, an electronic health record system covering US military personnel and their family members is used for this study, as well as data from HealthCore Integrated Research Database (HIRD<sup>SM</sup>), a healthcare payer claims database. The use of these data will provide insight into the risk of SLD and ILD in a non-interventional, "real world" setting.

---

\* Atrial flutter (AFL) was removed from this Protocol to reflect the indication listed in the current product label. AFL, as an indication, was removed from the product label dated December 2011. Data from the Dronedarone Surveillance Study showed approximately 0.6% of patients in both the Serious Liver/Disease Study Cohort and the Interstitial Lung Disease Study Cohort with an AFL diagnosis only. Given the small percentage, it was decided to remove the AFL diagnosis from the original AF/AFL study definition.

## 2 STUDY OBJECTIVES

There are two primary objectives for this study:

- To compare rates of hospitalized serious liver injury/disease (**SLD**) in dronedarone-exposed patients versus five separate anti-arrhythmic comparator cohorts all treated for AF.
- To compare rates of hospitalized interstitial lung disease (**ILD**) in dronedarone-patients versus five separate anti-arrhythmic comparator cohorts all treated for AF.

## 3 STUDY DESIGN

### 3.1 STUDY COMMITTEES

This study is being conducted and coordinated by The Degge Group, Ltd. (Degge) located in Fairfax, Virginia, USA. It will be carried out under the joint leadership of Degge in collaboration with the sponsor, Sanofi. It includes two data sources, appropriate committees for monitoring and safety of study progress, and adjudication of outcome events. Each committee has its' own charter with written roles and responsibilities and has written minutes of all committee meetings.

#### 3.1.1 Epidemiology Steering Committee

An external Epidemiology Steering Committee (ESC) has been convened to provide scientific oversight and advice on the Epidemiologic Study Protocol. The scientific management of this process consists of member identification, Charter development and approval, administrative management (e.g., contracting with experts, travel and accommodation arrangements), and Committee meeting management.

##### 3.1.1.1 Epidemiology Steering Committee Member Identification

An odd number of members were selected. ESC members, who are experts in their fields, include hepatologists, epidemiologists, statisticians, regulatory drug safety experts with experience in liver injury, and cardiologists. Panel members serve for the term of the study, which is estimated to last for approximately two years. The committee expects to meet at least two to three times a year.

#### **Epidemiology Steering Committee Membership:**

Judith K Jones, MD, PhD, FISPE, **Chair**  
*The Degge Group, Ltd., Fairfax, Virginia*

Rhonda L Bohn, ScD, MPH, FISPE, **Co-Chair**  
*Rhonda L Bohn, LLC, Boston, Massachusetts*

(Jean) Toby Barbey, MD, *Cardiologist*  
*Social Scientific Sciences, Silver Spring, Maryland*

(John) Michael Gaziano, MD, MPH, *Cardiologist/Epidemiologist*  
*Brigham & Women's Hospital, Boston, Massachusetts*

[NOTE: Resigned as of Aug 25, 2014. A replacement was not identified.]

James H. Lewis, MD, *Hepatologist*  
*Georgetown University, Washington, District of Columbia*

Captain Sally Tamayo, MD, *Cardiologist*,  
*Navy Medical Center, US Department of Defense, Portsmouth, Virginia*

Susan T. Sacks, PhD, FISPE, *Epidemiologist/Statistician*  
*Independent, Scottsdale, Arizona*

### **3.1.1.2      *Epidemiology Steering Committee Charter***

A description of the ESC and its mandate is described in the Charter. The Charter outlines the general topics and formats of the meetings over time. Committee meetings are held either face-to-face or held via teleconference. Two to three (2 - 3) subsequent annual meetings are anticipated; additional teleconferences or meetings will be determined on an as needed basis.

### **3.1.1.3      *Administrative Management of Epidemiology Steering Committee***

Degge will provide Agenda items, which will include a list of topics to be discussed at Epidemiology Steering Committee meetings. Degge is responsible for providing meeting materials to all participants prior to scheduled Epidemiology Steering Committee meetings as well as recording meeting minutes and disseminating the minutes to all participants.

## **3.1.2 Independent Adjudication Panel (IAP)**

Two separate IAPs will be convened, one for each outcome event; IAP-SLD, IAP-ILD.

### **3.1.2.1   *IAP Member Identification***

An odd number of members will be selected for the two Panels; one devoted to hepatic outcomes, the other, pulmonary. Three Panel members will be identified with a goal of having at least two specialists in each Panel representing the two therapeutic areas (liver Injury, pulmonary disease). Ideally, a representative from the US Department of Defense will be included as a member of each of the IAPs. Members will serve for the term of the study, which is estimated to last for approximately two years.

**IAP-SLD** members include:

- Willis C. Maddrey, MD, *Assistant to the President*, UT Southwestern Medical Center, Dallas, Texas,
- Natalie GB Murray, MD, *Medical Director - Liver Transplantation*, Baylor All Saints Medical Center, Texas, Fort Worth, Texas,

- Mark Russo, MD, MPH, *Medical Director of Liver Transplantation, Chief, Division of Hepatology*, Carolinas Medical Center, Charlotte, North Carolina.

**IAP-ILD** members include:

- Kevin R. Flaherty, MD, MS, *Professor of Internal Medicine*, University of Michigan Health System, Ann Harbor, Michigan,
- David J. Lederer, MD, MS, *Associate Medical Director, NYP/Columbia Lung Transplant Program*, Columbia University Medical Center, New York, New York,
- Ganesh Raghu, MD, *Director, Center of Interstitial Lung Disease*, University of Washington Medical Center, Seattle, Washington.

### **3.1.2.2 IAP Charter**

For each IAP, a Charter will be written which will describe the Panel's role and responsibilities, the adjudication process, and voting rules.

### **3.1.2.3 IAP Procedures**

Procedures for outcome event review and adjudication will be defined in a separate document and based on this protocol.

### **3.1.2.4 Administrative Management of IAP**

Degge will coordinate the outcome event review for the Adjudication Panels, and will be responsible for convening all Adjudication Review Meetings to reconcile differences in outcome event assignments. Degge will also be responsible for recording meeting minutes and disseminating the minutes to all participants.

## **3.2 STUDY DESCRIPTION**

An observational retrospective cohort design will be used to estimate the rate of SLD and ILD, separately. This protocol will cover both study outcomes with separate analyses conducted for each outcome. Further, separate analyses for each outcome event will be conducted in each data source (DoD and HIRD<sup>SM</sup>).

## **3.3 SOURCE POPULATIONS / DATABASES**

Two healthcare data environments will be used for this study:

- United States Department of Defense (DoD), Military Health System electronic health record system;
- HealthCore Integrated Research Database (HIRD<sup>SM</sup>), which is a healthcare payer claims database.

The results from each database will be reported separately.



### 3.3.1 US Department of Defense Military Health System Database

The source population for this study will include all members in the United States Department of Defense (DoD) Military Health System's (MHS) electronic health record system, which includes health care data for active duty members and their families (beneficiaries).

The MHS provides two types of care to its beneficiaries. It provides *direct care* through a network of 65 military hospitals and 411 clinics, and *purchased care* provided by civilian providers financed through managed care contracts and fee-for-service reimbursements. Direct care accounts for 37% of the total care provided with the balance being purchased from civilian providers. All the administrative events generated by either a direct care or purchased care encounter are centrally processed into the MHS Data Repository (MDR). Examples of the data recorded in such encounters include patient demographic data, provider information (provider ID, specialty, facility), diagnostic codes (ICD-9-CM codes for outpatient; Diagnosis-Related Group (DRG) codes for inpatient) and Current Procedural Terminology (CPT) codes for any procedures. Extensive information regarding the patient including address, age, race, rank, active duty status is also stored within the MDR via connections with the Defense Eligibility Enrollment Reporting System (DEERS). The military utilizes an electronic medication ordering system called the Pharmacy Data Transaction System (PDTs). All the prescribing details of both direct care and purchased care outpatient medication orders are electronically coded including the prescribed drug name and National Drug Code (NDC), dose, quantity, refills and prescribing provider.

#### Health ResearchTx, LLC / Department of Defense

Health ResearchTx (HRTx), a health research organization that has a unique partnership with the DoD to leverage the DoD healthcare system to improve health outcomes, lower costs, and increase force readiness, facilitates access to the DoD data extracts. Data access is provided to Degge through a secured server by encrypted login and password. HRTx is responsible for obtaining DoD Institutional Review Board or Ethics Board required approvals for this protocol.

### 3.3.2 HealthCore Integrated Research Database (HIRD<sup>SM</sup>)

The HealthCore Integrated Research Database (HIRD<sup>SM</sup>) will also be used for this study. The HIRD<sup>SM</sup> is currently a broad, clinically rich and geographically diverse spectrum of longitudinal insurance claims data from WellPoint and non-WellPoint health insurance plans in the Northeastern, Mid-Atlantic, Southeastern, Midwest, Central, and Western regions of the United States. It contains data on eligibility, medical, and pharmacy claims on more than 45 million members of one of the largest commercially insured populations in the United States. In addition, electronic laboratory results data are available for a subset of approximately 10 million patients. Outpatient and inpatient clinical data contained in the HIRD<sup>SM</sup> are coded with International Classification of Disease (ICD) diagnosis and procedure codes, Current Procedural Terminology (CPT<sup>®</sup>) codes, and the Healthcare Common Procedure Coding System (HCPCS). Outpatient medications are coded with National Drug

Codes (NDCs) as well as with Generic Product Indicators (GPI), which include the drug name, dosage form and drug strength.

At this time, data in the HIRD<sup>SM</sup> are available for 14 plans between January 1, 2006 and March 31, 2014. There are generally two types of patients who exist in the HIRD. The first are termed fully insured and for these patients the insurer (WellPoint) assumes the responsibility for all risk of the plan. The second population is termed administrative services only (ASO) and for these patients the employer assumes responsibility for all risk of the plan and the employer only purchases administrative services from the insurer.

These differences are administrative, however, and there is not expected to be any differences in terms of the claims completeness or availability of claims profile details for adjudication between these two subgroups of patients. Hence, both the fully insured and ASO patients can be successfully used for the epidemiology study.

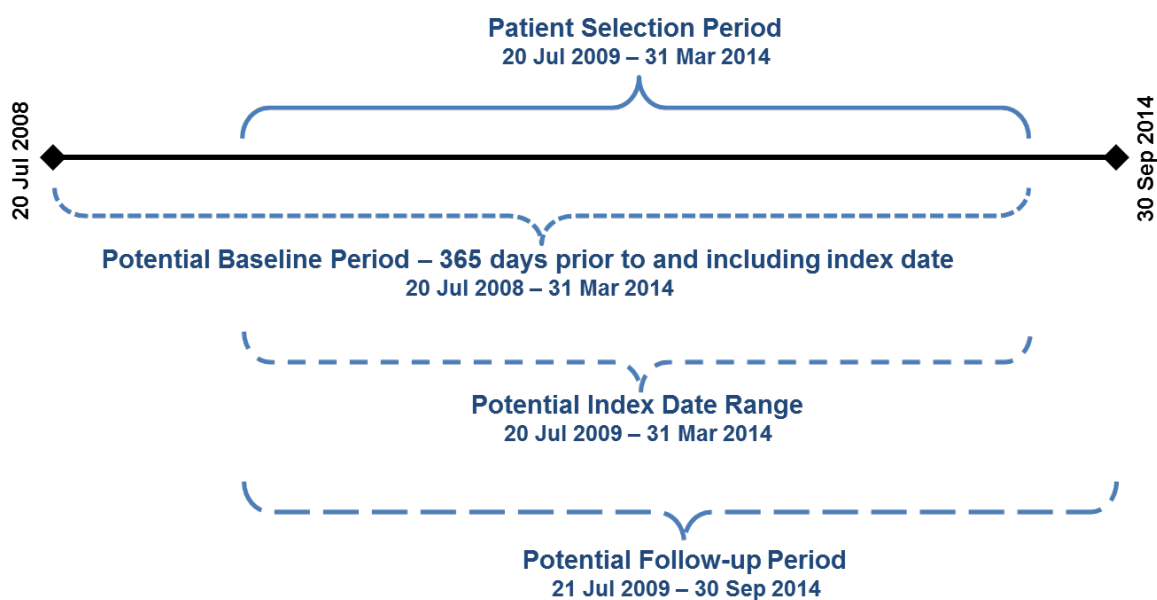
### 3.4 STUDY POPULATION

New users of dronedarone, amiodarone, sotalol, flecainide, dofetilide, and propafenone will define the Study Drug Cohorts.

#### 3.4.1 Study Period

Study start date - July 20, 2008, study end date – September 30, 2014. The baseline period is defined as 365 days prior to and including the index date. See [Figure 1](#).

**Figure 1. Patient Selection**



### 3.4.2 Inclusion / Exclusion Criteria

Patients must meet the following criteria to be included in the final Study Drug Cohorts.

#### 3.4.2.1 Inclusion Criteria

- A new prescription dispensed for any of the following anti-arrhythmic agents: **dronedarone, amiodarone, sotalol, flecainide, dofetilide, or propafenone** dispensed between July 20, 2009 (the dronedarone launch date in the US) and March 31, 2014 (See [Appendix A.1](#)). The earliest occurrence among these drugs of interest observed will determine the **index study cohort** assignment, and the date of the first study medication within the assigned cohort will be defined as the **Index Date**;
- No use of the index study drug during the baseline period. Use of non-index study drugs during baseline period is allowed;
- Patients aged 18 years and older as of their index date;
- 365 days of continuous eligibility prior to and including the index date;
- Diagnosed with atrial fibrillation (AF, ICD-9-CM diagnosis code 427.31) during the baseline period.

#### 3.4.2.2 Exclusion Criteria

- Unknown gender;
- Index study drug use during the baseline period;
- Less than 365 days of continuous eligibility prior to and including the index date;
- Absence of a diagnosis of AF during the baseline period;
- A diagnosis for cancer, organ transplant, HIV, or women who were pregnant or became pregnant during the baseline period (See [Appendix A.2](#)).

### 3.4.3 Additional Screening

Each final Study Drug Cohort will further exclude patients with baseline occurrences of the outcome event of interest and outcome-related conditions, separately, to better ensure that the outcome event post index is truly an incident outcome event and not a recurrence of one from the baseline period. This results in separate outcome event study cohorts.

#### 3.4.3.1 Serious Liver Injury/Disease Cohort Screening

To create the SLD Study Cohorts – patients in the final Study Drug Cohorts with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc...) of the following conditions ([Appendix B.1](#)):

- Serious liver injury/disease outcome event;
- History of viral hepatitis; or

- History of hereditary conditions (e.g., Wilson's disease, hemochromatosis, galactosemia, Alagille syndrome, alpha-1 antitrypsin deficiency, type 1 glycogen storage disease)

will be excluded. The remaining patients form the SLD Study Cohorts.

#### **3.4.3.2 Interstitial Lung Disease Cohort Screening**

For ILD – a narrow and a broad outcome event definition will be used. To create the ILD-Narrow Study Cohorts – patients in the final Study Drug Cohorts with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc...) of the following diseases ([Appendix C.1.1](#)):

- Interstitial lung disease outcome event – narrow definition;
- History of pneumonia; or
- History of sarcoidosis

will be excluded. The remaining patients form the ILD-Narrow Study Cohorts.

A sensitivity analysis will be conducted that uses a broader definition of ILD for baseline exclusionary screening and suspected outcome event identification.

To create the ILD-Broad Study Cohorts for the broader ILD definition – patients in the final Study Drug Cohorts with any baseline occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc...) of the following diseases ([Appendix C.2.1](#)):

- Interstitial lung disease outcome event – broad definition;
- History of pneumonia; or
- History of sarcoidosis

will be excluded. The remaining patients form the ILD-Broad Study Cohorts.

### **3.5 TREATMENT EPISODES, PATIENT FOLLOW-UP AND RISK PERIODS**

A **treatment episode** will be defined as a continuous period starting on the date a study drug is dispensed, and continuing for the duration of the prescription's days' supply. In cases where there is a gap of fewer than 30 days between the date on which a prescription's days' supply ends, and the dispensing date of a subsequent prescription for the same drug, the subsequent prescription will be considered a continuation of the first treatment episode.

A treatment episode ends on the date of the end of days' supply for the last prescription in the episode, plus 30 days (added as a risk window to account for potential non-compliance or missed doses). In cases where a different study drug is dispensed (switch treatment) prior to the end of a treatment episode (i.e., a treatment episode for the new drug begins), the end date of the first episode will be changed to the day preceding the start of the new switch treatment episode. A treatment episode end date will also be changed to the earliest of date of death, end of health plan eligibility or end of study, should any of those events occur prior to the calculated end of a treatment episode.

The **index treatment episode** will be the episode that begins on a patient's index date. See [Figure 2](#).

**Follow-up period** begins with the day after the index date and ends at the first occurrence of either the end of the study period, end of eligibility, or death.

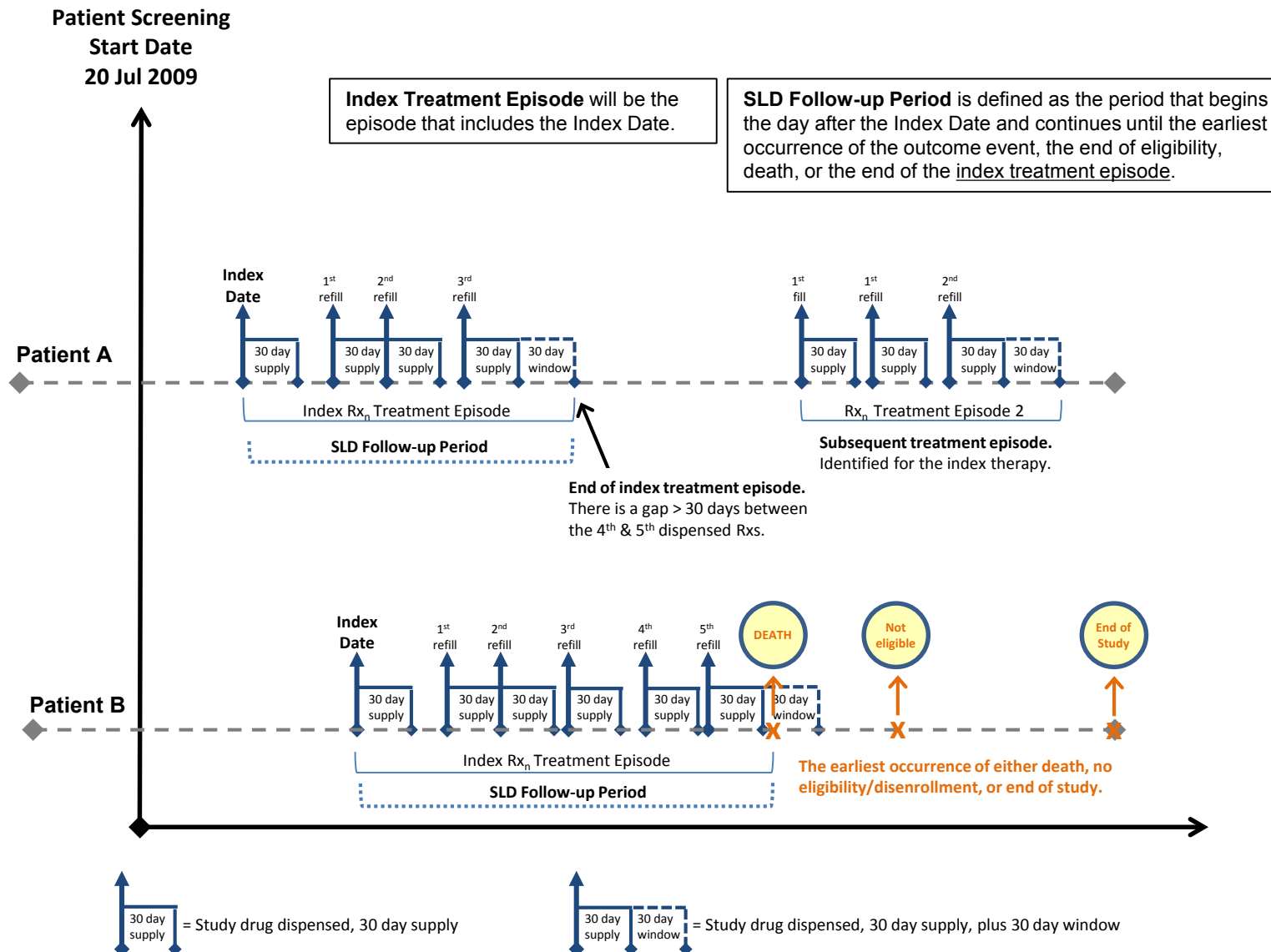
Risk Periods for each of the outcome events of interest are defined as follows:

**SLD Risk Period** is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the index treatment episode.

**ILD Risk Period 1** is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the study period.

**ILD Risk Period 2 (sensitivity analysis)** is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the outcome, the end of eligibility, death, or the end of the index treatment episode.

**Figure 2. Index Treatment Episode Identification / SLD Follow-up Period Identification**



### 3.6 OUTCOME EVENTS OF INTEREST

The two outcome events of interest are incident cases associated with a hospitalization for:

- Serious liver injury/disease (SLD) during the SLD Risk Period;
- Interstitial lung disease (ILD) during ILD Risk Period 1.

Each outcome event will be analyzed separately; therefore, an occurrence of one outcome event does not censor the follow up for the other outcome event. Only the first hospitalized outcome event occurrence will be assessed in each of the respective outcome event analyses. Hospitalizations will be restricted to acute care hospital and skilled nursing facility settings only.

#### 3.6.1 SERIOUS LIVER INJURY/DISEASE (SLD) OUTCOME EVENT

Suspected SLD outcome events will be identified by inpatient ICD-9-CM diagnosis / procedure codes, or CPT<sup>®</sup> procedure codes (see [Appendix B.2](#)). The date of the first hospitalized occurrence of one of these codes must occur within the SLD Risk Period to be selected for adjudication.

##### 3.6.1.1 Identifying Suspected SLD Outcome Events for Adjudication

Within the SLD Study Cohorts, suspected SLD outcome events will be identified via a diagnostic-specific algorithm for adjudication review based on the occurrence of ICD-9-CM diagnosis and procedure codes, or CPT<sup>®</sup> codes within the SLD Risk Period. See [Figure 3](#).

Patients will be selected for adjudication review if the first occurrence of any of the following codes appears among the hospital discharge diagnoses (from the facility record), occurring within the SLD Risk Period. The admission date of the hospitalization with an SLD defining code must fall within the SLD Risk Period. The following codes reflect liver injury/disease and will be referred to as **Group A Codes** ([Appendix B.3](#)):

##### **ICD-9-CM Diagnosis Codes (does not need to be Primary Discharge Diagnosis)**

570 Acute and subacute necrosis of liver  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
V42.7 Liver replaced by transplant

##### **ICD-9-CM Procedures Codes**

50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver

##### **CPT<sup>®</sup> Procedure Codes**

47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole

CPT Copyright 2013 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

A second set of codes, **Group B Codes** ([Appendix B.4](#)) which reflect highly suspicious, suggestive serious liver disease will also trigger adjudication review. Occurrence of the following ICD-9-CM diagnosis codes after the index date must be a primary inpatient discharge diagnosis (from the facility record), to select patients for adjudication review. The procedure codes may occur in any position during an inpatient stay for that patient. The admission date of the hospitalization with an SLD defining code must fall within the SLD Risk Period.

**ICD-9-CM Diagnosis Codes (must be primary discharge diagnosis):**

277.4 Disorders of bilirubin excretion  
 571.5 Cirrhosis of liver without mention of alcohol  
 572.8 Other sequelae of chronic liver disease  
 573.0 Chronic passive congestion of liver  
 573.3 Hepatitis, unspecified  
 573.8 Other specified disorders of liver  
 573.9 Unspecified disorder of liver  
 782.4 Jaundice, unspecified  
 794.8 Nonspecific abnormal results of liver function test

**ICD-9-CM Procedure Codes**

50.11 Closed (percutaneous) [needle] biopsy of liver  
 50.12 Open biopsy of liver  
 50.13 Transjugular liver biopsy  
 50.14 Laparoscopic liver biopsy  
 50.91 Percutaneous aspiration of liver

**CPT® Procedure Codes**

47000 Biopsy of liver, needle; percutaneous  
 47001 Biopsy of liver, needle; done at time of other major procedure  
 47100 Biopsy of liver, wedge  
 78205 Liver imaging (SPECT)  
 78206 Liver imaging (SPECT); with vascular flow

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The codes used to define the SLD outcome event (Group A and Group B) were based on a definition previously developed by K Arnold Chan et al, 2003<sup>5</sup> but were slightly modified. Removed from the SLD definition was 789.1 Hepatomegaly, and 791.4 Biliuria; and one code was included – 572.8 Other sequelae of chronic liver disease. The Group A codes were validated for the Mini-Sentinel Project by V. Lo Re et al. 2013.<sup>6</sup> [Appendix B.5](#) provides a flowchart that illustrates the algorithm to select patients for SLD adjudication review.

### 3.6.2 INTERSTITIAL LUNG DISEASE (ILD)

Suspect ILD outcome events will be identified based on inpatient ICD-9-CM diagnosis codes only. The first hospitalization within the Risk period with a discharge diagnosis code meeting the outcome event definition will be identified as the suspect ILD outcome event. The ILD diagnosis code does not need to be the primary discharge diagnosis (from the facility



record). The admission date of that first hospitalization will be assigned as the suspect ILD outcome event date. Patients will only be counted once for the ILD outcome event regardless of subsequent occurrences of ILD outcome event diagnoses.

### 3.6.2.1 Identifying Suspected ILD Outcome Events for Adjudication

ILD may manifest itself within a few days or weeks after exposure, or take longer to appear (e.g., months or years). Due to ILD's non-specific clinical presentations, a broad range of diagnoses may be assigned to ILD patients. In consideration of these complexities, two definitions (narrow and broad) will be used to define suspected ILD outcome events. Also, two Risk periods will be screened given the timeframe in which it manifests itself. **Table i** lists the primary analysis and the sensitivity analyses that will be conducted in the DoD database for the ILD outcome event. [HealthCore will conduct the sensitivity analyses in HIRD upon request]. Also, [Figure 4a](#) and [Figure 4b](#) illustrate the suspected ILD selection process.

**Table i. Analyses to be conducted for ILD Outcome Event**

| Analysis Type                                                         | ILD Definition | Observation Timeframe |
|-----------------------------------------------------------------------|----------------|-----------------------|
| Primary analysis (follow-up until end of study)                       | Narrow         | ILD Risk Period 1     |
| Sensitivity analysis (follow-up until end of index treatment episode) | Narrow         | ILD Risk Period 2     |
| Sensitivity analysis (follow-up until end of study)                   | Broad          | ILD Risk Period 1     |
| Sensitivity analysis (follow-up until end of index treatment episode) | Broad          | ILD Risk Period 2     |

#### ILD Narrow Outcome Event Definition

The ILD outcome event – narrow definition is the primary focus for this analysis. The narrow definition ([Appendix C.1.2](#)) is based on the codes described in a systematic review for the Mini-Sentinel Project by Natalie Jones et al. 2012.<sup>7</sup> ILD Risk Period 1 will be screened for the following codes, any of which must be a hospital discharge diagnosis code (from the facility record, any position) to be selected:

#### **ILD Narrow Definition - ICD-9-CM Diagnosis Codes**

- 515 Post-inflammatory pulmonary fibrosis
- 516.3 Idiopathic fibrosing alveolitis
  - 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
  - 516.31 Idiopathic pulmonary fibrosis (IPF)
  - 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
  - 516.33 Acute interstitial pneumonitis (AIP)
  - 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
  - 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
  - 516.36 Cryptogenic organizing pneumonia (COP)

- 516.37 Desquamative interstitial pneumonia (DIP)
- 516.8 Other specified alveolar and parietoalveolar pneumonopathies
- 516.9 Unspecified alveolar and parietoalveolar pneumonopathy

ILD Risk Period 2, which mirrors the index treatment episode timeframe, will be screened for outcome events using the same ILD narrow definition.

There is little literature that provides administrative and claims data-based definitions / coding algorithms to identify ILD. None of the ICD-9-CM codes listed above have been validated. Use of these codes may not provide the desired levels of sensitivity and specificity.

[Appendix C.1.3](#) illustrates the process to select patients based on the narrow definition for ILD adjudication review.

#### ILD Broad Outcome Event Definition

The ILD Broad outcome event definition, defined below and in [Appendix C.2.2](#), will be used to screen for suspected ILD outcome events in both ILD Risk Period 1 and ILD Risk Period 2. The following codes define ILD Broad outcome events, any of which must be a hospital discharge diagnosis code (from the facility record, any position) to be selected:

#### **ILD Broad Definition - ICD-9-CM Diagnosis Codes**

- 495.9 Unspecified allergic alveolitis and pneumonitis
- 515 Post-inflammatory pulmonary fibrosis
- 516.3 Idiopathic fibrosing alveolitis
  - 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
  - 516.31 Idiopathic pulmonary fibrosis (IPF)
  - 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
  - 516.33 Acute interstitial pneumonitis (AIP)
  - 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
  - 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
  - 516.36 Cryptogenic organizing pneumonia (COP)
  - 516.37 Desquamative interstitial pneumonia (DIP)
- 516.8 Other specified alveolar and parietoalveolar pneumonopathies
- 516.9 Unspecified alveolar and parietoalveolar pneumonopathy
- 518.82 Other pulmonary insufficiency, not elsewhere classified (e.g., adult respiratory distress syndrome)

As noted above, none of the ICD-9-CM codes listed above have been validated. [Appendix C.2.3](#) illustrates the process to select patients for suspected ILD Broad outcome event adjudication review.

### 3.7 ADJUDICATION OF OUTCOME EVENTS

Any patient with one or both suspected outcome events identified will have his/her medical history surrounding the suspected event(s) reviewed by the respective Adjudication Panels. The adjudication process will involve a manual review of all medical and prescription history related to the study outcomes. The data will be formatted in such a manner that all diagnoses, procedures, non-study drug dispensings, and other available data will be presented chronologically for each outcome event for Panel Members to review.

Adjudication Panel Members will be blinded to study drug exposure (drug name, quantity, and formulation), as well as all patient-identifying information. Patient-related documents will be codified with an encrypted patient number. Each member will independently review each case and determine, given the patient profile characteristics and timing of the outcome event relative to the blinded study drug's exposure, whether the suspected outcome event was likely to have occurred.

Each Adjudication Panel member will indicate their determination from the list below for each suspected outcome:

- **“Yes”** – the patient profile contains diagnostic/procedural coding that meets the outcome event criteria,
- **“No”** – the patient profile does not have diagnostic/procedural coding that meets the outcome event criteria, or
- **“Indeterminate”** – the patient profile does not have diagnostic/ procedural coding that meets the outcome event criteria, but the clinical picture suggests an outcome event may have occurred.

Panel member decisions will be tabulated for each outcome event. Outcome events with unanimous agreement will have that determination assigned in the database. No further discussion will be needed. If disagreement between the Panel members exists, the patient profile will be discussed in a formal meeting where all three Panel members and the Chair are present. The Chair will lead the discussion. Each panel member will present their reasoning for their decision, followed by a final vote. If the final decision vote is unanimous then that decision will be assigned to that outcome event in the database; otherwise the outcome event will be assigned as “Indeterminate”.

**Figure 3. Identifying Patients with Suspected SLD Outcome Event during the SLD Risk Period for Adjudication**

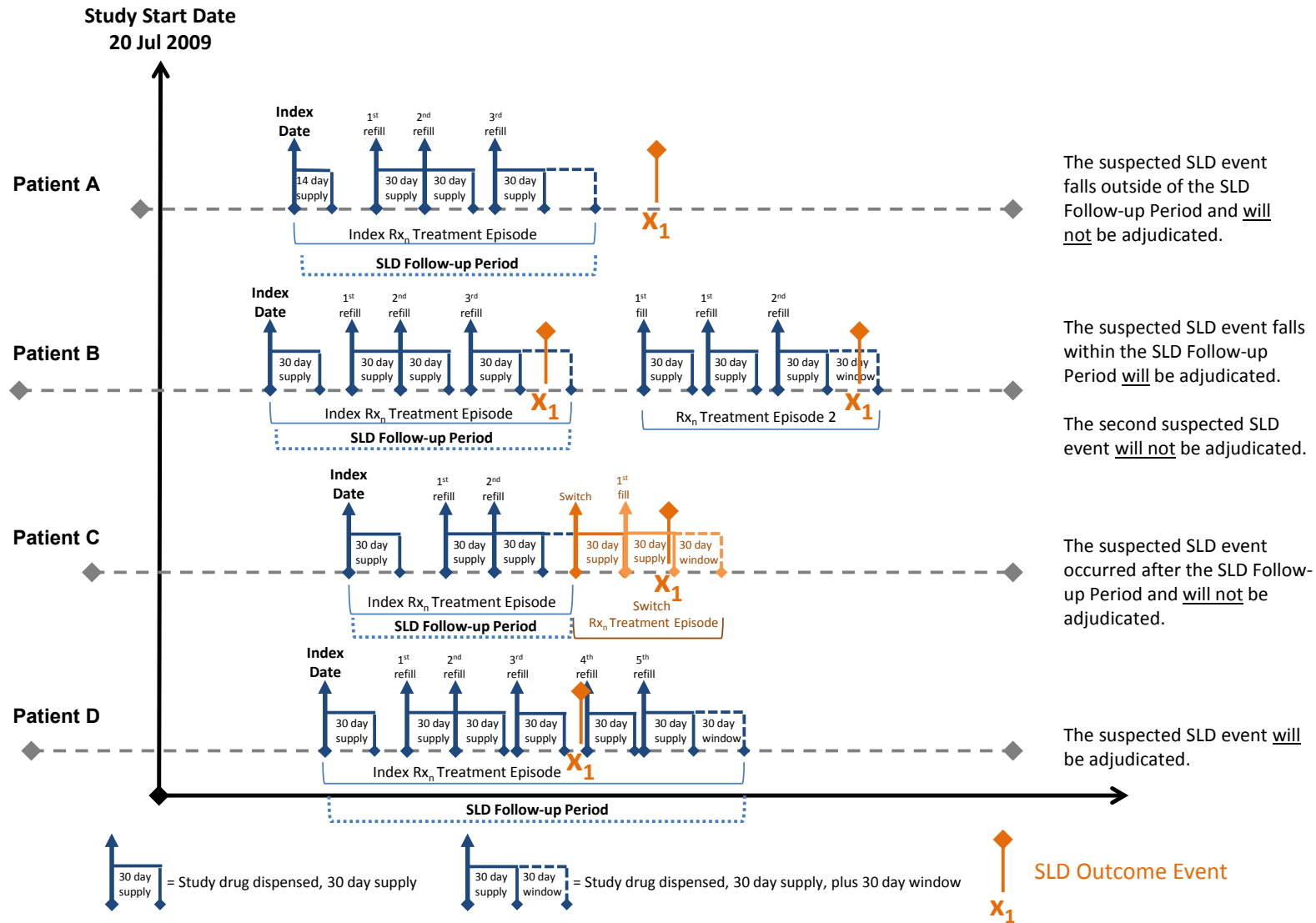


**Figure 4a. Identifying Patients with Suspected ILD Outcome Event during the ILD Risk Period 1 for Adjudication**

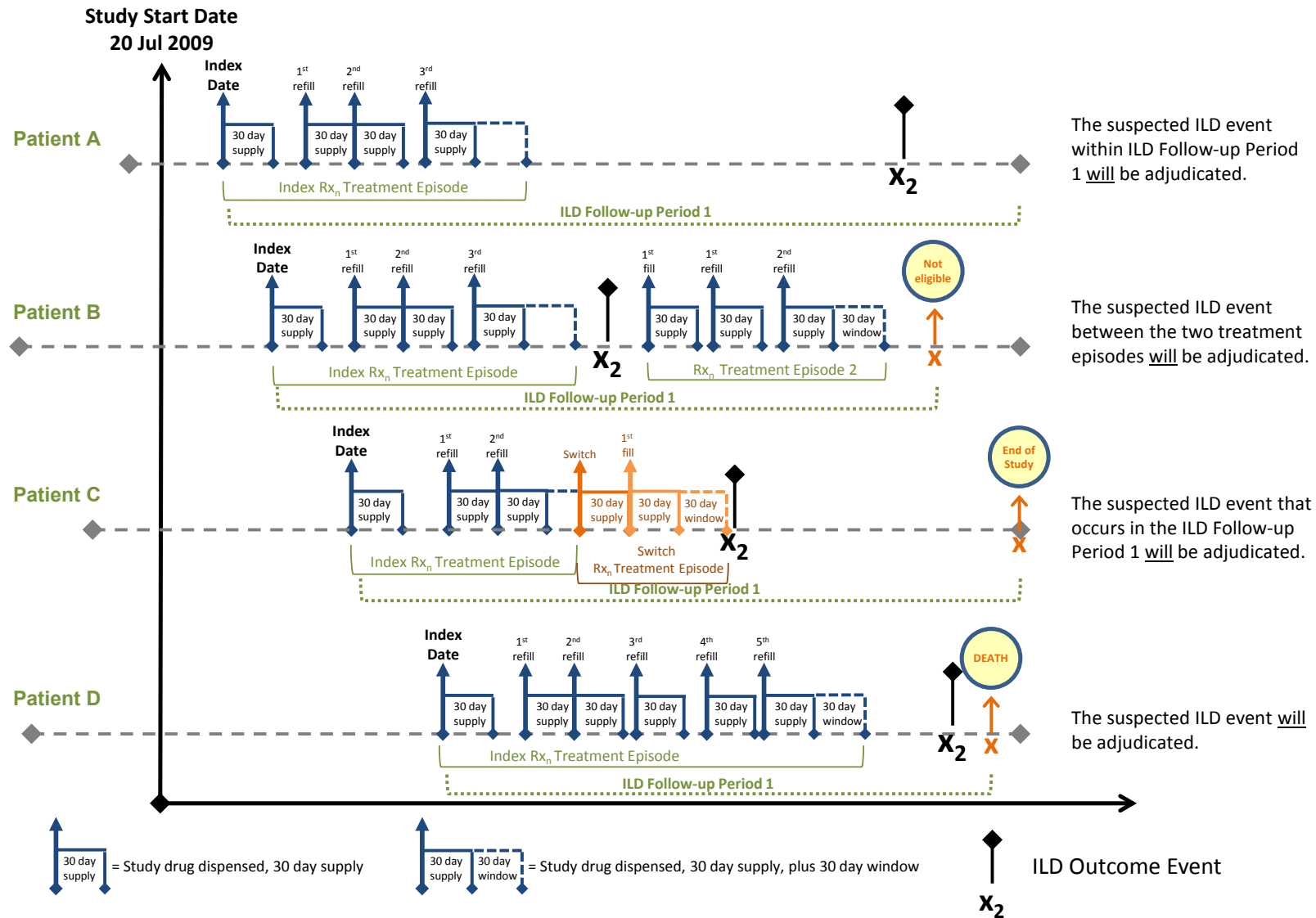
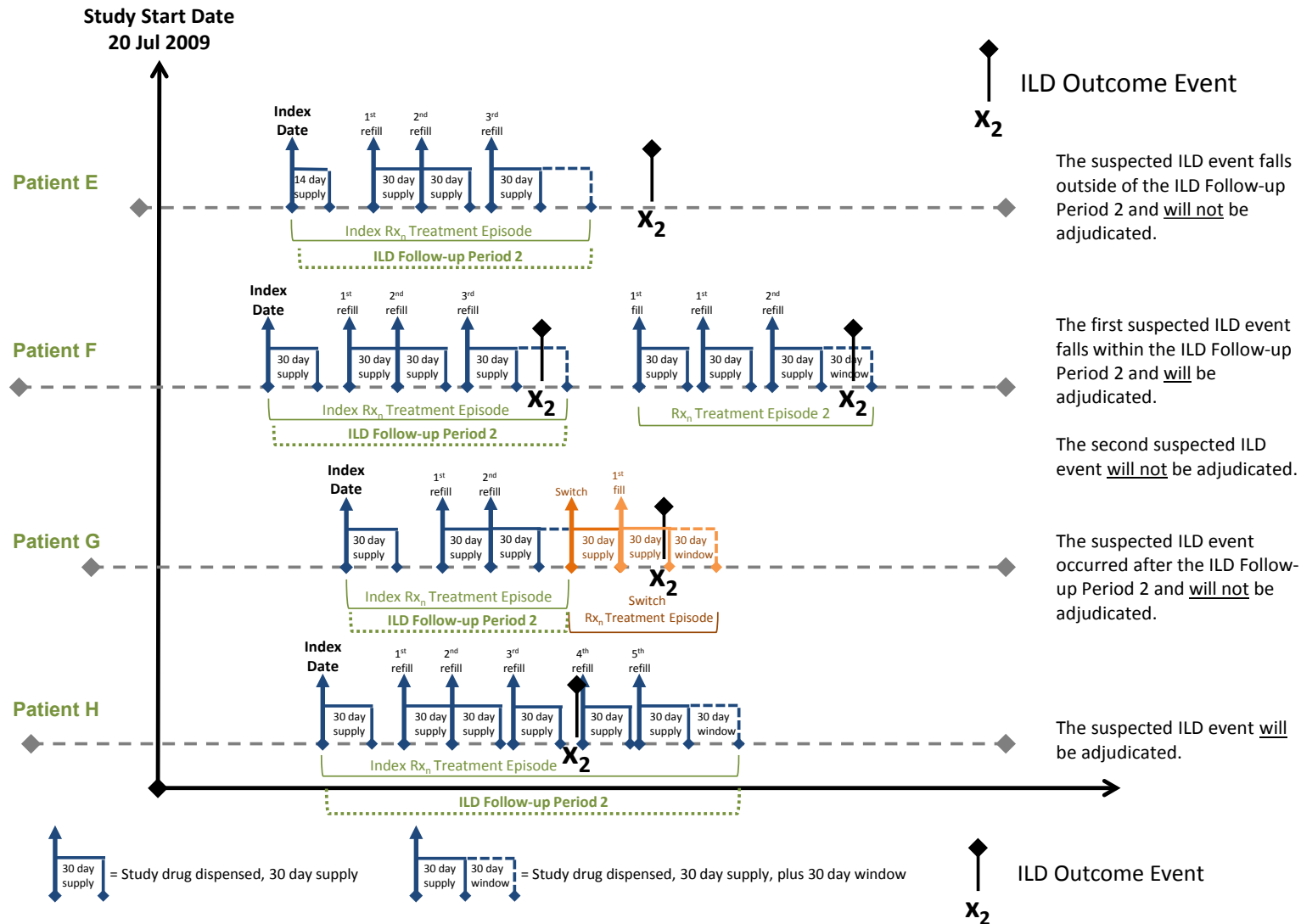


**Figure 4b. Identifying Patients with Suspected ILD Outcome Event during the ILD Risk Period 2 for Adjudication**



## 3.8 COVARIATES

### 3.8.1 Confounder Definition

A confounder is a variable that is related to both the exposure and the outcome event of interest.

### 3.8.2 Identification of Possible Confounders/Risk Factors

These variables will be identified in each data source in their respective eligibility files or notes, ICD-9-CM diagnosis or procedure codes, and/or medication files.

#### 3.8.2.1 *SLD, potential risk factors/confounders include (See [Appendix D](#))*<sup>8</sup>:

- History of Alcoholism;
- History of Bile duct disorders;
- History of Congestive heart failure;
- History of Diabetes;
- History of Obesity;
- Prior use of hepatotoxic medications.\*

\* Systemic use only.

#### 3.8.2.2 *ILD, potential risk factors/confounders include (See [Appendix E](#))*<sup>9</sup>:

- History of Asthma;
- History of Bronchitis, excluding acute bronchitis;
- History of Chronic obstructive pulmonary disease;
- History of Connective tissue disease;
- History of Exposure to occupational and environmental toxins;
- History of Gastroesophageal reflux disease;
- Prior use of agents associated with drug-induced pulmonary disease<sup>\*10</sup>;
- Prior use of Therapeutic oxygen treatment.

\* Systemic use only.

### 3.8.3 Handling of confounders

Propensity score matching will be used to balance known confounders for this study. See [Section 4.1 Propensity Score Matching](#).

### 3.9 SAMPLE SIZE AND POWER CALCULATION

The following chart shows the number of dronedarone subjects required to provide 80% power, at the 0.05 alpha level, to detect hazard ratios of 2.0, 3.0, and 4.0, for various values of the comparator (reference) group incidence rate:

| Incidence Rate, % / year Events / 100 patient-years In the Comparator Group | # of Subjects Needed in Each Cohort |              |        |
|-----------------------------------------------------------------------------|-------------------------------------|--------------|--------|
|                                                                             | HR=2.0                              | HR=3.0       | HR=4.0 |
| 0.01%/year (1 / 10,000 patient-years)                                       | 108,947                             | 38,553       | 22,698 |
| 0.02%/year (1 / 5,000 patient-years)                                        | 54,477                              | 19,278       | 11,351 |
| 0.05%/year (1 / 2,000 patient-years)                                        | 21,800                              | 7,714        | 4,542  |
| 0.1%/year (1 / 1,000 patient-years)                                         | 10,906                              | <b>3,860</b> | 2,273  |
| 0.2%/year (1 / 500 patient-years)                                           | 5,460                               | 1,933        | 1,138  |
| 0.5%/year (1 / 200 patient-years)                                           | 2,192                               | 776          | 457    |
| 1%/year (1 / 100 patient-years)                                             | 1,103                               | 391          | 231    |

[Software: PS - Power and Sample Size Calculations, version 3.0, by W. D. Dupont and W. D. Plummer (Vanderbilt University).]

The sample-size requirements were estimated based on the following statistical design parameters and assumptions:

- **Type of Analysis:** Comparison of event-free “survival” time between the dronedarone-exposed cohort and a comparator (reference) cohort, by means of the log-rank test, or Cox proportional-hazards regression
- **Alpha Level:** 0.05 ( $p \leq 0.05$  considered statistically significant)
- **Power:** 80% (80% chance of obtaining a significant result if a true difference in event-free survival between cohorts exists, and is of an important magnitude)
- **Effect Size of Importance:** Hazard Ratio = 3.0
- **Incidence Rate in the Comparator (Reference) Group:** 1 event/1,000 patient-years
- **Group size Ratio:** 1:1 (equal numbers of dronedarone and comparator subjects), consistent with 1:1 propensity-score matching
- **Accrual Interval:** 5 years (July 2009 through March 2014)
- **Follow-up Beyond Last Accrual:** 0 months (index dates can range from July 2009 through September 2014)

Initial baseline characteristics will be reported for each of the six cohorts. Cohorts that do not meet the sample size requirement will not be subject to propensity score matching. Initial baseline characteristics will be presented but no further analysis will be conducted.



Background data to support the sample size and power calculations:

Data were provided by Sanofi from an internal Sanofi-conducted study (Safety Study Report – Dronedarone, SR33589, GPE Pharmacoepidemiology, August 2, 2011). The study found the following:

| Outcome Studied                              | Incidence Rate /<br>1000 PYs |
|----------------------------------------------|------------------------------|
| Incidence of acute liver injury <sup>‡</sup> | 7.6 (0.9 - 14.2)             |
| Incidence of interstitial lung disease       | 21.9 (10.5 - 33.4)           |

<sup>‡</sup> Defined as a primary dx of acute or sub-acute necrosis of liver, hepatic coma, toxic hepatitis, or liver transplant in hospital by ICD-9-CM and CPT codes.

It is reasonable to state that 1 per 1,000 PYs is a conservative estimate used in the sample size calculations. Therefore, for a HR of 3.0, the required sample size is 3,860 in each patient group.

## 4 STATISTICAL ANALYSIS

In order to compare rates of serious liver injury/disease and interstitial lung disease between cohorts, patients in each of the five comparator cohorts will be propensity score matched to patients in the dronedarone cohort. Since dronedarone is the newest drug to the market and there are likely selection factors that influence the decision to initiate treatment with this drug (as well as the decision to treat with the other study drugs), propensity score matching will be utilized to balance, as much as possible, known measureable confounders that may influence drug selection.

### 4.1 PROPENSITY SCORE MATCHING

Propensity score matching (PSM) is a statistical technique that attempts to isolate the estimated effect of a treatment or exposure by accounting for the covariates that predict the likelihood of the exposure. PSM employs a predicted probability of exposure based on observed predictors, usually obtained from logistic regression. The technique provides a close adjustment for differences in covariates at baseline and thereby reduces bias due to confounding variables that could be found in an estimate of the exposure effect obtained from simply comparing outcomes among exposed subjects (in this case, the dronedarone cohort) versus unexposed subjects (the comparator cohorts).

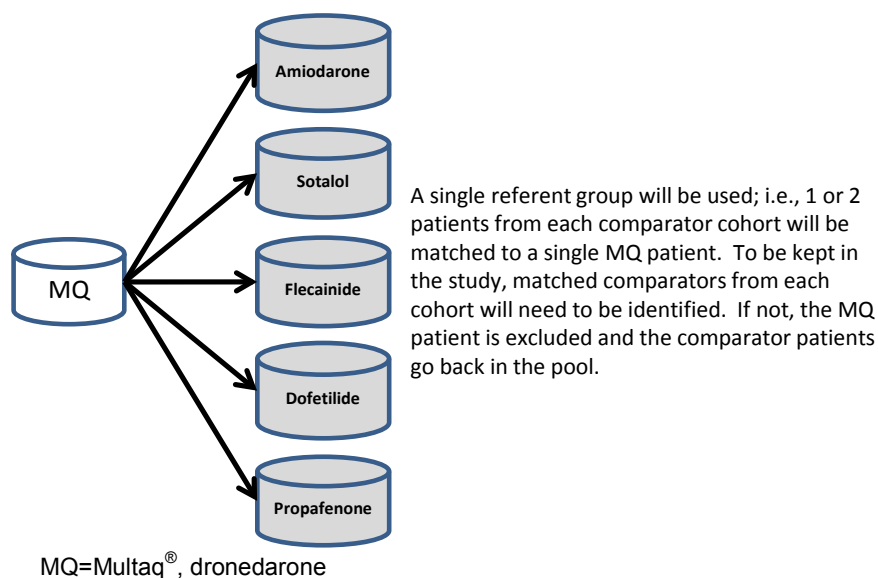
An attempt will be made to match one patient from each of the five comparator cohorts (amiodarone, sotalol, flecainide, propafenone, and dofetilide) to each patient in the dronedarone cohort according to propensity score (PS). The matching will be conducted without replacement. Specifically, five separate subsets of the DoD and HealthCore database, each containing all of the dronedarone patients and patients from one of the comparator cohorts will be created. The same reduced logistic model (derived from the dataset combining all cohorts) will be independently fitted to each of the subsets and the results used to calculate propensity scores for each patient in the subset. Within each subset, the absolute difference between PS scores of each dronedarone and comparator patient will be calculated. Selecting dronedarone patients in random order, the closest patient in each comparator cohort will be selected for matching (from remaining comparators not already matched to another dronedarone patient). If matches for a given dronedarone subject, are not found across all comparator groups then the dronedarone subject will be considered unmatchable and excluded from the analysis. (See [Figure 5](#).)

For the dataset of matched patients baseline covariate distributions should be essentially identical for all cohorts, and dronedarone users and their comparators can be compared using transparent, simpler unmatched methods that do not require adjustments for confounders. For example, Kaplan-Meier event-free survival curves can be compared between cohorts with a log-rank test.

The exact PSM process will be described fully in a separate Statistical Analysis Plan (SAP).

[Appendix F](#) contains the initial list of variables to be included in the PSM Model.

**Figure 5. Propensity Score Matching**



For this study a nearest-neighbor-within-caliper matching algorithm will be employed.

## 4.2 EVALUATION OF PROPENSITY SCORE MODEL AND MATCHING

The adequacy of PS-based matching can be assessed in several ways:

- The goodness of fit of the logistic model will be examined using Lemeshow<sup>11</sup> test for calibration and by the C-statistic for discrimination.
- For caliper-based PS-matching, the choice of caliper width should be justified by sensitivity analysis of a range of caliper widths, demonstrating that the chosen width strikes an acceptable balance between number of potential matches and closeness of the match (described below).
- The baseline values of the potential confounders will be examined to ensure comparability across the matched cohorts using standard differences or other appropriate tests.
- The differences in outcome event measures between cohorts should not vary systematically with PS, as assessed by comparing the results of analyses stratified by PS-quintile, or by including PS as a covariate in a multivariate analysis of the outcome.

### 4.2.1 Fit of the Logistic Model

The adequacy of the logistic model to represent the observed dependence of exposure on the baseline values of the available potential confounders will be checked in several ways.

- The fit will be evaluated graphically. All records will be sorted by PS and a graph will be prepared of the cumulative sum of the PS values (y) will be generated, vs. the corresponding cumulative fraction of subjects who were actually in the exposed category (x). If the data actually conforms to the fitted logistic model, the plotted points should lie exactly along a straight diagonal line between (0,0) and (1,1).
- The adequacy of the logistic fit will also be evaluated inferentially by the Lemeshow test for calibration and by the C statistic for discrimination.

#### **4.2.2 Effect of Caliper Width**

The log-odds of the probability calculated by the reduced logistic regression model will be used as the PS. (The log-odds is the linear portion of the logistic model, prior to transformation into a probability.) Caliper width for nearest-neighbor matching will be based on a fraction of the standard deviation of the PS. Several caliper-width strategies will be evaluated, and a choice will be made so as to achieve an acceptable tradeoff between poor matching (caliper too wide) and excessive exclusion from the matched population (caliper too narrow).

#### **4.2.3 Balance of Baseline Values between Matched Cohorts**

Tables summarizing baseline values of the potential confounders for patients in each of the matched cohorts will be generated (mean, standard deviation, median, etc.). Standardized differences will be calculated to compare the balance of baseline covariate values between the dronedarone patients and patients in each comparator cohort (means for continuous variables and proportions for dichotomous variables) both before and after PS matching. Groups will be considered balanced if the absolute value of the standardized difference between the dronedarone group and each comparator group is less than 0.1 for all of the variables.

#### **4.2.4 Variability of Hazard Ratios with PS for the Primary Outcome**

Unlike randomization, which (in the long run) will compensate for the effects of all known and unknown confounders between groups, PS matching can hope to compensate only for known confounders that are included in the PS model. Therefore, even in a study where PS-matching has been executed perfectly, and the cohorts are completely balanced for all known confounders, the outcome event can be affected by unknown confounders that remain unbalanced between cohorts. This is an intrinsic limitation of PS matching. This will be tested for in two ways:

- Running analyses stratified by PS-based groups (such as quartiles or quintiles), and checking whether the outcomes vary systematically across the sequenced strata.
- Incorporating the PS as a covariate (with interaction terms between PS and the cohorts), and checking whether the coefficients of the interaction terms are significantly different from zero.

If PS-dependence of outcomes is observed, it means that the effect of comparator drug on the outcome, relative to dronedarone, could be biased by the unknown (and uncompensated) confounders, and must be interpreted with caution.

### 4.3 ANALYTIC APPROACH

#### 4.3.1 Descriptive Summaries

Data will be tabulated to show (see [Section 7 Tables and Figures](#)), for each outcome, for each exposure group:

- The number of subjects with and without the event, the proportion of subjects with the event with its 95% confidence interval, and the p-value for the comparison of event proportions between the comparator drugs and dronedarone (by the Fisher Exact Test<sup>12</sup>).
- The number of patient-years of observation, the number of incident events, raw event rate with its 95% confidence interval, and the p-value for the comparison of event rates between the comparator drugs and dronedarone. This comparison will be done using hazard ratios.
- Hospitalizations prior to the index date will be identified and tabulated, as well as their proximity to the index date for stratification purposes or for further analysis.
- Adjudicated outcome events:
  - Stratified by “Yes”, “No”, and “Indeterminate” decisions;
  - Stratified by different variables: demographic, concomitant drug, concomitant diseases;
  - Stratified according to latency periods: 1 month, >1 to 6 months, > 6 months continuous exposure from the index date;
  - Exploratory evaluation of potential confounders.

#### 4.3.2 Controlling for Type-1 Errors

In this safety study, the Type 1 error rate will be controlled to a 0.05 test-wise alpha level. Significance will be inferred for any analysis in which the p-value is less than 0.05 for the comparison between the dronedarone cohort and a comparator (reference) cohort. No adjustments for multiple comparisons will be applied.

The EMA says the following about multiplicity in testing safety variables:

“In the case of adverse effects, p-values are of very limited value, [because] substantial differences (expressed as relative risk or risk differences will raise concern, depending on seriousness, severity or outcome, irrespective of the p-value observed.

In those cases where a large number of statistical test procedures are used to serve as a flagging device to signal a potential risk caused by the investigational drug, it can

generally be stated that an adjustment for multiplicity is counterproductive for considerations of safety. It is clear in that in this situation there is no control over the type I error for a single hypothesis, and the importance and plausibility of such results will depend on prior knowledge of the pharmacology of the drug.”

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003640.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003640.pdf)

### **4.3.3 Survival Analyses**

#### **4.3.3.1 *Cox proportional-hazards regression analysis***

Separate Cox regression<sup>14</sup> models will be carried out for each outcome, with exposure group (dronedarone as the reference drug) as the main independent variable, and incorporating any other covariates of interest that were not included in the propensity score. Results will be presented as adjusted hazard ratios, with 95% confidence intervals and p-values, for each comparator drug relative to dronedarone.

The following analyses will be conducted for both ILD Definitions. Since ILD outcome events will be identified throughout the risk period, an outcome event may occur after a study drug switch. The primary ILD analysis will be based on an intention to treat approach that will count exposure from the index date through to the end of follow-up. A sensitivity analysis will be conducted looking only at the index treatment episode for ILD outcomes.

The Schoenfeld residual test will be performed to test the proportionality assumption of all analyses.<sup>15</sup>

#### **4.3.3.2 *Kaplan Meier Survival Estimates***

Kaplan-Meier survival curves will be prepared and graphed, with one graph for each outcome event (i.e., SLD, ILD-primary, ILD-secondary), displaying separate survival curves for each exposure group.<sup>13</sup> The log-rank test will be performed to determine if there is a statistically significant difference in the curves.

### **4.3.4 Sensitivity Analyses (DoD Dataset Only)**

#### **4.3.4.1 *Addition of laboratory data to SLD***

An additional sensitivity analysis will be performed on the SLD subset of the population that have available laboratory test results (e.g., alanine transaminase levels, aspartate transaminase levels, bilirubin levels) to 1) to determine if it is representative of the database population, and 2) to determine if this information adds value to the existing data.

#### **4.3.4.2 *Addition of smoking data to ILD***

If possible, an additional sensitivity analysis will be performed on the ILD subset of the population that has available smoking status information (e.g., smoker, non-smoker).

#### **4.3.5 Combination of results from separate databases**

The databases have structural and content differences that preclude the simple pooling of subjects from both databases for matching and analysis. These differences cannot be mitigated by simply including a database-identification categorical variable as a covariate in the survival model. Analyses will be run separately for each database, and the results of the analyses (hazard ratios, confidence intervals, p values, etc.) will be described.

Individual database analyses will not likely be conducted in parallel. The epidemiological study will begin with the DoD database, followed by the HIRD<sup>sm</sup> database when sample size targets have been reached. The Table below highlights the anticipate99d timelines for both databases.

p. 600



## 6 REFERENCES

1. Multaq® [package insert]. Bridgewater, NJ: Sanofi; 2014.
2. Treatment Guidelines from the Medical Letter. 2010;8(97):65-70.
3. Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Heuzey J-Y L, Kay GN, Lowe SE, Olsson SB, Prystowsky EN, Tamargo JL, Wann S. ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation—Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines: *Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society*. 2006 *Circulation*:114: 700-752.
4. Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Kay GN, Le Heuzey J-Y, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann LS. 2011 ACCF/AHA/HRS focused updates incorporated into the ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;123:e269–e367.
5. Chan KA, Truman A, Gurwitz JH, Hurley JS, Martinson B, Platt R, Everhart JE, Moseley RH, Terrault N, Ackerson L, Selby JV. A cohort study of the incidence of serious acute liver injury in diabetic patients treated with hypoglycemic agents. *Arch Intern Med*. 2003 Mar 24;163(6):728-34.
6. Lo Re V, Haynes K, Goldberg D, Forde KA, Carbonari DM, Leidl KBF, et al. Validity of diagnostic codes to identify cases of severe acute liver injury in the U.S. Food and Drug Administration's Mini-Sentinel Distributed Database. *Pharmacoepidemiol Drug Safe*. 2013;22:861-872.
7. Jones N, Schneider G, Kachroo S, Rotella P, Avetisyan R, Reynolds MW. A systematic review of validated methods for identifying pulmonary fibrosis and interstitial lung disease using administrative and claims data. *Pharmacoepidemiol Drug Safe*. 2012;21(S1):256-260.
8. <http://www.healthcommunities.com/liver-disease/causes.shtml>. Accessed May 17, 2013.
9. <http://www.mayoclinic.com/health/interstitial-lung-disease/DS00592/DSECTION=risk-factors>. Accessed May 17, 2013.
10. Schwaiblmair M, Behr W, Haeckel T, Märkl B, Foerg W, Berghaus T. Drug induced interstitial lung disease. *Open Respir Med J*. 2012;6:63-74. doi: 10.2174/1874306401206010063.
11. Hosmer, David W.; Lemeshow, Stanley (2000). *Applied Logistic Regression*. New York: Wiley. [ISBN 0-471-61553-6](#).

12. Fisher, R. A. (1922). "On the interpretation of  $\chi^2$  from contingency tables, and the calculation of P". [\*Journal of the Royal Statistical Society\*](#) 85(1): 87–94.
13. Kaplan, E. L.; Meier, P. (1958). "Nonparametric estimation from incomplete observations". *Journal of the American Statistical Association*. 53(282): 457–481.
14. Cox, D. R.; Oakes, D. (1984). *Analysis of Survival Data*. New York: Chapman & Hall.
15. Schoenfeld D. (1980). Chi-squared goodness-of-fit tests for the proportional hazards regression model. *Biometrika* **67**(1):145-153.

## **7 TABLES AND FIGURES**

The following tables and figures are examples of the intended output to be reported for each outcome event of interest within each data source for this study.

**SLD-Table 1: Baseline Characteristics Of Patients In Each Of The SLD Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)             | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|------------------------------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| Age at cohort entry date, Mean(SD) |                      |                     |                  |                     |                     |                      |
| 18-39 years                        |                      |                     |                  |                     |                     |                      |
| 40-49 years                        |                      |                     |                  |                     |                     |                      |
| 50-59 years                        |                      |                     |                  |                     |                     |                      |
| 60-69 years                        |                      |                     |                  |                     |                     |                      |
| 70-79 years                        |                      |                     |                  |                     |                     |                      |
| 80+ years                          |                      |                     |                  |                     |                     |                      |
| Gender (female)                    |                      |                     |                  |                     |                     |                      |
| Race                               |                      |                     |                  |                     |                     |                      |
| White                              |                      |                     |                  |                     |                     |                      |
| Asian or Pacific Islander          |                      |                     |                  |                     |                     |                      |
| Black                              |                      |                     |                  |                     |                     |                      |
| American Indian/Alaskan Native     |                      |                     |                  |                     |                     |                      |
| Other                              |                      |                     |                  |                     |                     |                      |
| Unknown                            |                      |                     |                  |                     |                     |                      |
| <b>History of Disease</b>          |                      |                     |                  |                     |                     |                      |
| Deyo-Charlson Index                |                      |                     |                  |                     |                     |                      |
| Alcoholism                         |                      |                     |                  |                     |                     |                      |
| Bile Duct Disorders                |                      |                     |                  |                     |                     |                      |
| Congestive Heart Failure           |                      |                     |                  |                     |                     |                      |
| Diabetes                           |                      |                     |                  |                     |                     |                      |
| Obesity                            |                      |                     |                  |                     |                     |                      |
| <b>History of Medication Use</b>   |                      |                     |                  |                     |                     |                      |
| Other Anti-arrhythmic Agents       |                      |                     |                  |                     |                     |                      |
| Hepatotoxic medications            |                      |                     |                  |                     |                     |                      |

**SLD-Table 2: Follow-up Time In Each of The SLD Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Follow-up Time* | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|-----------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| 1 - 90 days     |                      |                     |                  |                     |                     |                      |
| 91 - 180 days   |                      |                     |                  |                     |                     |                      |
| 181 - 365 days  |                      |                     |                  |                     |                     |                      |
| 366 - 545 days  |                      |                     |                  |                     |                     |                      |
| 546 - 730 days  |                      |                     |                  |                     |                     |                      |
| >730 days       |                      |                     |                  |                     |                     |                      |
| Average         |                      |                     |                  |                     |                     |                      |
| Median          |                      |                     |                  |                     |                     |                      |
| SD              |                      |                     |                  |                     |                     |                      |
| Min             |                      |                     |                  |                     |                     |                      |
| Max             |                      |                     |                  |                     |                     |                      |

\*Calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**SLD-Table 3: Number of Index Drug Treatment Episodes and Number of Non-Index Study Drug Dispensed In Each Of The SLD Study Cohorts: DoD Database – July 20, 2009 to September 30, 2014**

| Drug Treatment Episodes       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|-------------------------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| Index Drug Treatment Episodes |                      |                     |                  |                     |                     |                      |
| 1 Episode                     |                      |                     |                  |                     |                     |                      |
| 2 Episodes                    |                      |                     |                  |                     |                     |                      |
| 3 Episodes                    |                      |                     |                  |                     |                     |                      |
| 4+ Episodes                   |                      |                     |                  |                     |                     |                      |
| Average                       |                      |                     |                  |                     |                     |                      |
| Median                        |                      |                     |                  |                     |                     |                      |
| SD                            |                      |                     |                  |                     |                     |                      |
| Min                           |                      |                     |                  |                     |                     |                      |
| Max                           |                      |                     |                  |                     |                     |                      |

**Number of Non-Index Study Drugs Dispensed Post Index Date**

1  
2  
3  
4

**SLD-Table 4: Baseline Characteristics Of Patients In Each Of The SLD Study Cohorts After Propensity Score Modeling: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)              | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------|----------------------|---------------------|------------------|---------------------|
| Age at cohort entry date, Mean (SD) |                      |                     |                  |                     |
| 18-39 years                         |                      |                     |                  |                     |
| 40-49 years                         |                      |                     |                  |                     |
| 50-59 years                         |                      |                     |                  |                     |
| 60-69 years                         |                      |                     |                  |                     |
| 70-79 years                         |                      |                     |                  |                     |
| 80+ years                           |                      |                     |                  |                     |
| Gender (female)                     |                      |                     |                  |                     |
| Race                                |                      |                     |                  |                     |
| White                               |                      |                     |                  |                     |
| Asian or Pacific Islander           |                      |                     |                  |                     |
| Black                               |                      |                     |                  |                     |
| American Indian/Alaskan Native      |                      |                     |                  |                     |
| Other                               |                      |                     |                  |                     |
| Unknown                             |                      |                     |                  |                     |
| <b>History of Disease</b>           |                      |                     |                  |                     |
| Deyo-Charlson Index                 |                      |                     |                  |                     |
| Alcoholism                          |                      |                     |                  |                     |
| Bile Duct Disorders                 |                      |                     |                  |                     |
| Congestive Heart Failure            |                      |                     |                  |                     |
| Diabetes                            |                      |                     |                  |                     |
| Obesity                             |                      |                     |                  |                     |
| <b>History of Medication Use</b>    |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents        |                      |                     |                  |                     |
| Hepatotoxic medications             |                      |                     |                  |                     |

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**SLD-Table 5: Standardized Differences In PS Model Covariates Between SLD Dronedarone And Comparator Cohorts Before And After PS Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Covariates                                        | SLD Study Cohorts Before PS Matching |    |    |    |                     |     |     | SLD Analysis Dataset After PS Matching |     |     |     |                   |     |     |
|---------------------------------------------------|--------------------------------------|----|----|----|---------------------|-----|-----|----------------------------------------|-----|-----|-----|-------------------|-----|-----|
|                                                   | Mean Value or %                      |    |    |    | 100*Difference / SD |     |     | Mean Value or %                        |     |     |     | 100*Difference SD |     |     |
|                                                   | MQ                                   | AM | SO | FL | iAM                 | iSO | iFL | mMQ                                    | mAM | mSO | mFL | iAM               | iSO | iFL |
| Gender (% Female)                                 |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Age on index date (mean)                          |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Days from start of study to patient Index Date    |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Alcoholism                                        |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Bile Duct Disorders                               |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Congestive Heart Failure                          |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Diabetes                                          |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Obesity                                           |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Baseline use of other study medications           |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Baseline use of other anti-arrhythmic medications |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Baseline use of hepatotoxic medications           |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Number of Hospitalizations                        |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Number of Office visits                           |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Number of ER visits                               |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Number of different medications                   |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |
| Gastroenterology specialty visits                 |                                      |    |    |    |                     |     |     |                                        |     |     |     |                   |     |     |

MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Flecainide

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**SLD-Table 6: Follow-up Time for SLD Analysis Dataset After Propensity Score Matching:  
 DoD Database – July 20, 2009 to September 30, 2014**

| <b>Follow-up Time*</b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|------------------------------|
| 1 - 90 days            |                              |                             |                          |                             |                              |
| 91 - 180 days          |                              |                             |                          |                             |                              |
| 181 - 365 days         |                              |                             |                          |                             |                              |
| 366 - 545 days         |                              |                             |                          |                             |                              |
| 546 - 730 days         |                              |                             |                          |                             |                              |
| >730 days              |                              |                             |                          |                             |                              |
| Average                |                              |                             |                          |                             |                              |
| Median                 |                              |                             |                          |                             |                              |
| SD                     |                              |                             |                          |                             |                              |
| Min                    |                              |                             |                          |                             |                              |
| Max                    |                              |                             |                          |                             |                              |

\*Calculated as time from Index Date through to the earliest of either end of eligibility, end of study or date of death.  
 Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.



**SLD-Table 7: Numbers and Characteristics of Patients With Adjudicated SLD Outcome Events:  
DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics                         | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-----------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                        |                      |                     |                  |                     |
| Yes                                     |                      |                     |                  |                     |
| No                                      |                      |                     |                  |                     |
| Indeterminate                           |                      |                     |                  |                     |
| <b>Demographics*</b>                    |                      |                     |                  |                     |
| Age at cohort entry date, Mean (SD)     |                      |                     |                  |                     |
| 18-39 years                             |                      |                     |                  |                     |
| 40-49 years                             |                      |                     |                  |                     |
| 50-59 years                             |                      |                     |                  |                     |
| 60-69 years                             |                      |                     |                  |                     |
| 70-79 years                             |                      |                     |                  |                     |
| 80+ years                               |                      |                     |                  |                     |
| Gender (female)                         |                      |                     |                  |                     |
| Race                                    |                      |                     |                  |                     |
| White                                   |                      |                     |                  |                     |
| Asian or Pacific Islander               |                      |                     |                  |                     |
| Black                                   |                      |                     |                  |                     |
| American Indian/Alaskan Native          |                      |                     |                  |                     |
| Other                                   |                      |                     |                  |                     |
| Unknown                                 |                      |                     |                  |                     |
| <b>History of Disease</b>               |                      |                     |                  |                     |
| Deyo-Charlson Index                     |                      |                     |                  |                     |
| Alcoholism                              |                      |                     |                  |                     |
| Bile Duct Disorders                     |                      |                     |                  |                     |
| Congestive Heart Failure                |                      |                     |                  |                     |
| Diabetes                                |                      |                     |                  |                     |
| Obesity                                 |                      |                     |                  |                     |
| <b>History of Medication Use</b>        |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents            |                      |                     |                  |                     |
| Hepatotoxic medications                 |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date*</b> |                      |                     |                  |                     |
| Up to 1 month                           |                      |                     |                  |                     |
| 1 Month up to 6 months                  |                      |                     |                  |                     |
| Greater than 6 months                   |                      |                     |                  |                     |

\*Includes only "Yes" adjudicated outcome events. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

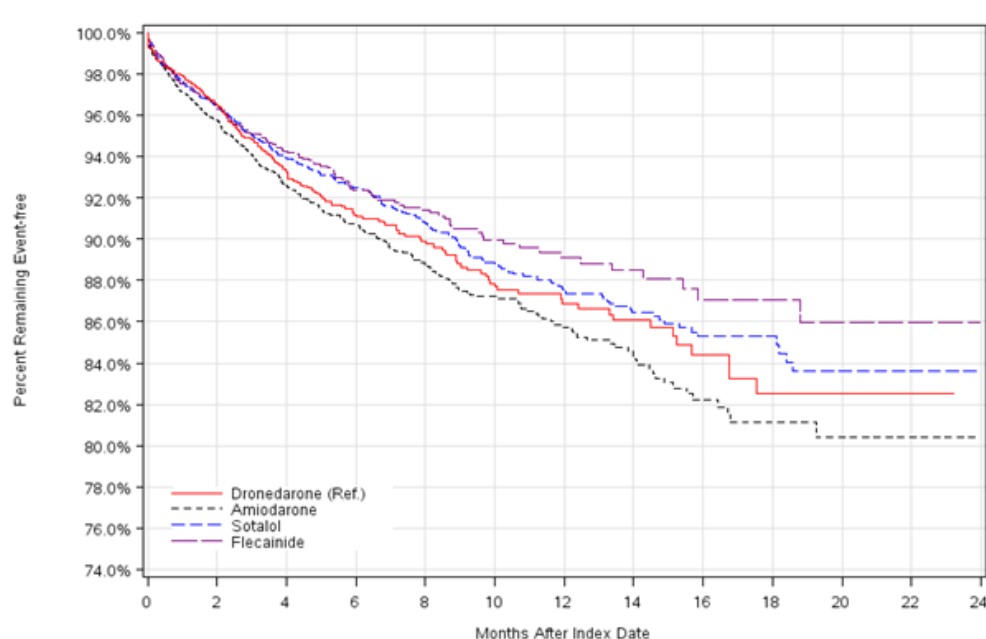
**SLD-Table 8: Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated SLD Outcome Events: DoD Database – July 20, 2009 to September 30, 2014**

|                         | Dronedarone | Amiodarone | Sotalol | Flecainide |
|-------------------------|-------------|------------|---------|------------|
| # Cases (Yes)           |             |            |         |            |
| # of Person-Years       |             |            |         |            |
| Incidence rate (95% CI) |             |            |         |            |
| Crude HR (95% CI)       | Reference   |            |         |            |
| Adjusted HR (95% CI)*   | Reference   |            |         |            |

\* Adjusted for ...

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**SLD-Figure 1: Sample Kaplan Meier Survival Curve of SLD Adjudicated Events: DoD Database – July 20, 2009 to September 30, 2014**



**Two** sets of ILD Tables will be provided. One set for ILD-Narrow definition and one set for the ILD-Broad definition.

Tables **ILD-Table 1.1** to **ILD-Table 1.8** contain the primary analysis for ILD-Narrow definition (looking at ILD-Narrow outcome events within Risk Period 1). Tables **ILD-Table 1.9** and **ILD-Table 1.10** display the results for a sensitivity analysis conducted on the ILD-Narrow definition but looking at ILD-Narrow outcome events within ILD Risk Period 2.

Tables **ILD-Table 2.1** - **ILD-Table 2.8** show the sensitivity analysis results for the ILD-Broad definition (looking at ILD-Broad outcome events within ILD Risk Period 1). Tables **ILD-Table 2.9** - **ILD-Table 2.10** display the results for a sensitivity analysis conducted on the ILD-Broad definition but looking at ILD-Broad outcome events within ILD Risk Period 2.

**ILD-Table 1.1: Baseline Characteristics Of Patients In Each Of The ILD-Narrow Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |                     |                      |
| 18-39 years                                           |                      |                     |                  |                     |                     |                      |
| 40-49 years                                           |                      |                     |                  |                     |                     |                      |
| 50-59 years                                           |                      |                     |                  |                     |                     |                      |
| 60-69 years                                           |                      |                     |                  |                     |                     |                      |
| 70-79 years                                           |                      |                     |                  |                     |                     |                      |
| 80+ years                                             |                      |                     |                  |                     |                     |                      |
| Gender (female)                                       |                      |                     |                  |                     |                     |                      |
| Race                                                  |                      |                     |                  |                     |                     |                      |
| White                                                 |                      |                     |                  |                     |                     |                      |
| Asian or Pacific Islander                             |                      |                     |                  |                     |                     |                      |
| Black                                                 |                      |                     |                  |                     |                     |                      |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |                     |                      |
| Other                                                 |                      |                     |                  |                     |                     |                      |
| Unknown                                               |                      |                     |                  |                     |                     |                      |
| History of smoking                                    |                      |                     |                  |                     |                     |                      |
| <b>History of Disease</b>                             |                      |                     |                  |                     |                     |                      |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |                     |                      |
| Asthma                                                |                      |                     |                  |                     |                     |                      |
| Bronchitis                                            |                      |                     |                  |                     |                     |                      |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |                     |                      |
| Connective Tissue Disease                             |                      |                     |                  |                     |                     |                      |
| Exposure to Toxins                                    |                      |                     |                  |                     |                     |                      |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |                     |                      |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |                     |                      |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |                     |                      |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |                     |                      |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |                     |                      |

**ILD-Table 1.2: Follow-up Time In Each of the ILD-Narrow Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Follow-up Time*</b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| 1 - 90 days            |                              |                             |                          |                             |                             |                              |
| 91 - 180 days          |                              |                             |                          |                             |                             |                              |
| 181 - 365 days         |                              |                             |                          |                             |                             |                              |
| 366 - 545 days         |                              |                             |                          |                             |                             |                              |
| 546 - 730 days         |                              |                             |                          |                             |                             |                              |
| >730 days              |                              |                             |                          |                             |                             |                              |
| Average                |                              |                             |                          |                             |                             |                              |
| Median                 |                              |                             |                          |                             |                             |                              |
| SD                     |                              |                             |                          |                             |                             |                              |
| Min                    |                              |                             |                          |                             |                             |                              |
| Max                    |                              |                             |                          |                             |                             |                              |

\*Calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**ILD-Table 1.3: Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed In Each Of The ILD-Narrow Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Drug Treatment Episodes</b>       | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|--------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| <b>Index Drug Treatment Episodes</b> |                              |                             |                          |                             |                             |                              |
| 1 Episode                            |                              |                             |                          |                             |                             |                              |
| 2 Episodes                           |                              |                             |                          |                             |                             |                              |
| 3 Episodes                           |                              |                             |                          |                             |                             |                              |
| 4+ Episodes                          |                              |                             |                          |                             |                             |                              |
| Average                              |                              |                             |                          |                             |                             |                              |
| Median                               |                              |                             |                          |                             |                             |                              |
| SD                                   |                              |                             |                          |                             |                             |                              |
| Min                                  |                              |                             |                          |                             |                             |                              |
| Max                                  |                              |                             |                          |                             |                             |                              |

**Number of Non-Index Study Drugs Dispensed Post Index Date**

|   |
|---|
| 1 |
| 2 |
| 3 |
| 4 |

**ILD-Table 1.4: Baseline Characteristics Of Patients In Each Of The ILD-Narrow Analysis Dataset After Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Table 1.5: Standardized Differences In PS Model Covariates Between ILD-Narrow Dronedarone And Comparator Cohorts Before And After PS Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Covariates                                                            | ILD Narrow Study Cohorts Before PS Matching |    |    |    |                     |     |     | ILD Narrow Analysis Dataset After PS Matching |     |     |     |                     |     |     |
|-----------------------------------------------------------------------|---------------------------------------------|----|----|----|---------------------|-----|-----|-----------------------------------------------|-----|-----|-----|---------------------|-----|-----|
|                                                                       | Mean Value or %                             |    |    |    | 100*Difference / SD |     |     | Mean Value or %                               |     |     |     | 100*Difference / SD |     |     |
|                                                                       | MQ                                          | AM | SO | FL | iAM                 | iSO | iFL | mMQ                                           | mAM | mSO | mFL | iAM                 | iSO | iFL |
| Gender (% Female)                                                     |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Age on index date (mean)                                              |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Days from start of study to patient Index Date                        |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Asthma                                                                |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Bronchitis                                                            |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Chronic Obstructive Pulmonary Disease                                 |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Connective Tissue Disease                                             |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Exposure to Toxins                                                    |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Gastroesophageal Reflux Disease                                       |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Baseline use of other study medications                               |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Baseline use of other anti-arrhythmic medications                     |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Baseline use of agents associated with drug induced pulmonary disease |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Baseline use of therapeutic oxygen treatment                          |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Number of hospitalizations                                            |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Number of office visits                                               |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Number of ER visits                                                   |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Number of different medications                                       |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |
| Pulmonology specialty visits                                          |                                             |    |    |    |                     |     |     |                                               |     |     |     |                     |     |     |

MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Flecainide

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Table 1.6: Follow-up Time for ILD-Narrow Analysis Dataset After Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Follow-up Time*</b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| 1 - 90 days            |                              |                             |                          |                             |
| 91 - 180 days          |                              |                             |                          |                             |
| 181 - 365 days         |                              |                             |                          |                             |
| 366 - 545 days         |                              |                             |                          |                             |
| 546 - 730 days         |                              |                             |                          |                             |
| >730 days              |                              |                             |                          |                             |
| Average                |                              |                             |                          |                             |
| Median                 |                              |                             |                          |                             |
| SD                     |                              |                             |                          |                             |
| Min                    |                              |                             |                          |                             |
| Max                    |                              |                             |                          |                             |

\*Calculated as time from Index Date through to the earliest of either end of eligibility, end of study or date of death.  
 Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.



**ILD-Table 1.7: Numbers and Characteristics of Patients With Adjudicated ILD-Narrow Outcome Events Identified During ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics*</b>                                  |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date*</b>               |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

\*Includes only "Yes" adjudicated outcome events. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

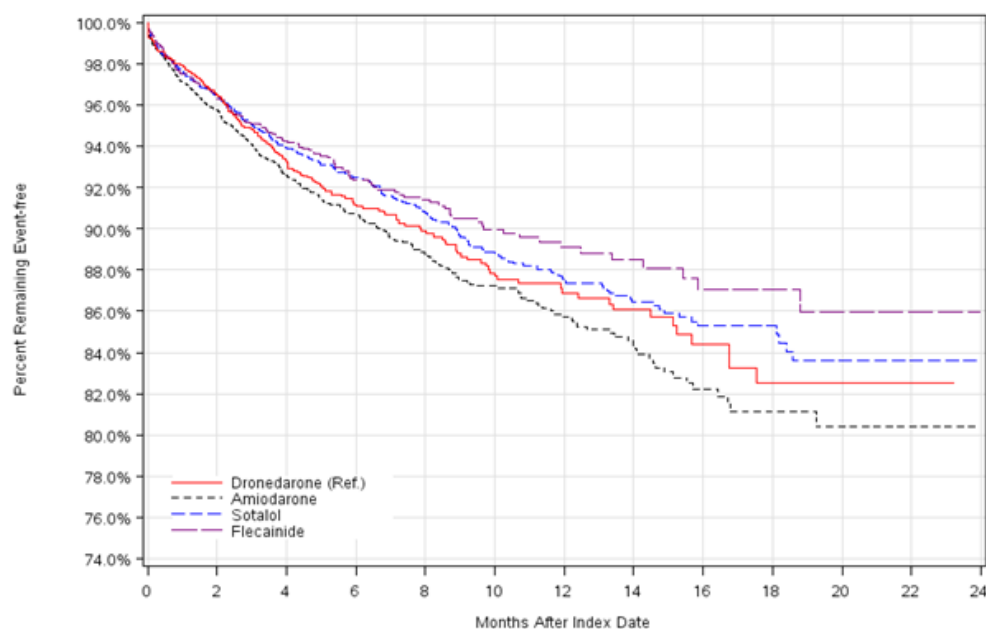
**ILD-Table 1.8: Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated ILD-Narrow Outcome Events Identified During ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**

|                         | Dronedarone | Amiodarone | Sotalol | Flecainide |
|-------------------------|-------------|------------|---------|------------|
| # Cases (Yes)           |             |            |         |            |
| # of Person-Years       |             |            |         |            |
| Incidence rate (95% CI) |             |            |         |            |
| Crude HR (95% CI)       | Reference   |            |         |            |
| Adjusted HR (95% CI)*   | Reference   |            |         |            |

\* Adjusted for ...

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Figure 1.1: Sample Kaplan Meier Survival Curve ILD-Narrow Adjudicated Events Identified During ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**



**ILD-Table 1.9: Characteristics of Patients with Adjudicated ILD-Narrow Outcome Events Identified During ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics*</b>                                  |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date*</b>               |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

\*Includes only "Yes" adjudicated outcome events. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

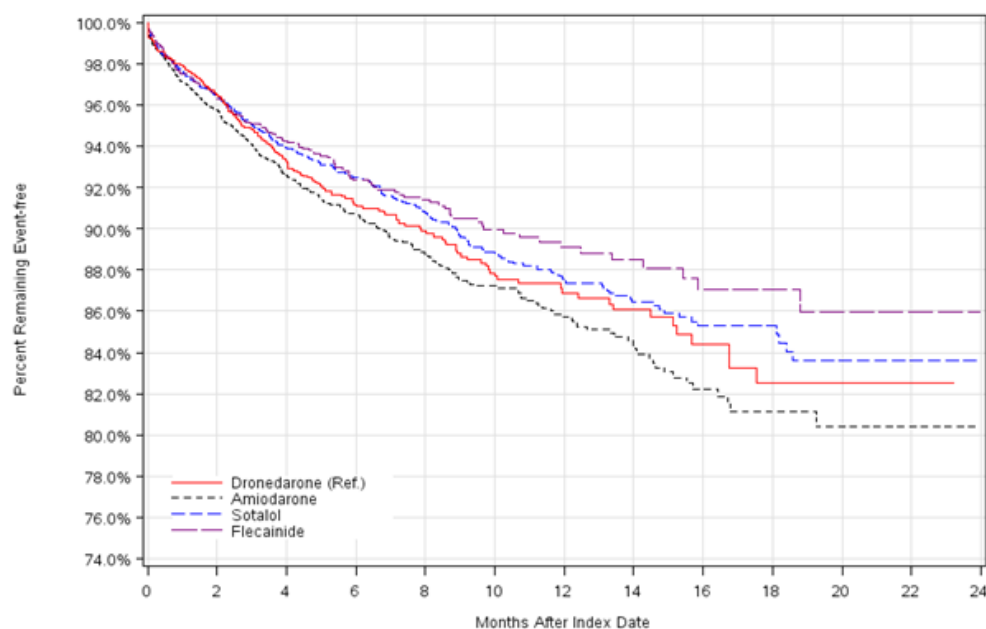
**ILD-Table 1.10: Incidence Rates (per 1000 person-years) and Hazard Ratio of Adjudicated ILD-Narrow Outcome Events Identified During ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**

|                         | Dronedarone | Amiodarone | Sotalolol | Flecainide |
|-------------------------|-------------|------------|-----------|------------|
| # Cases (Yes)           |             |            |           |            |
| # of Person-Years       |             |            |           |            |
| Incidence rate (95% CI) |             |            |           |            |
| Crude HR (95% CI)       | Reference   |            |           |            |
| Adjusted HR (95% CI)*   | Reference   |            |           |            |

\* Adjusted for ...

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Figure 1.2: Sample Kaplan Meier Survival Curve ILD-Narrow Adjudicated Events Identified During ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**



**ILD-Table 2.1: Baseline Characteristics Of Patients In Each Of The ILD-Broad Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |                     |                      |
| 18-39 years                                           |                      |                     |                  |                     |                     |                      |
| 40-49 years                                           |                      |                     |                  |                     |                     |                      |
| 50-59 years                                           |                      |                     |                  |                     |                     |                      |
| 60-69 years                                           |                      |                     |                  |                     |                     |                      |
| 70-79 years                                           |                      |                     |                  |                     |                     |                      |
| 80+ years                                             |                      |                     |                  |                     |                     |                      |
| Gender (female)                                       |                      |                     |                  |                     |                     |                      |
| Race                                                  |                      |                     |                  |                     |                     |                      |
| White                                                 |                      |                     |                  |                     |                     |                      |
| Asian or Pacific Islander                             |                      |                     |                  |                     |                     |                      |
| Black                                                 |                      |                     |                  |                     |                     |                      |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |                     |                      |
| Other                                                 |                      |                     |                  |                     |                     |                      |
| Unknown                                               |                      |                     |                  |                     |                     |                      |
| History of smoking                                    |                      |                     |                  |                     |                     |                      |
| <b>History of Disease</b>                             |                      |                     |                  |                     |                     |                      |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |                     |                      |
| Asthma                                                |                      |                     |                  |                     |                     |                      |
| Bronchitis                                            |                      |                     |                  |                     |                     |                      |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |                     |                      |
| Connective Tissue Disease                             |                      |                     |                  |                     |                     |                      |
| Exposure to Toxins                                    |                      |                     |                  |                     |                     |                      |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |                     |                      |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |                     |                      |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |                     |                      |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |                     |                      |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |                     |                      |

**ILD-Table 2.2: Follow-up Time In Each Of The ILD-Broad Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Follow-up Time*</b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| 1 - 90 days            |                              |                             |                          |                             |                             |                              |
| 91 - 180 days          |                              |                             |                          |                             |                             |                              |
| 181 - 365 days         |                              |                             |                          |                             |                             |                              |
| 366 - 545 days         |                              |                             |                          |                             |                             |                              |
| 546 - 730 days         |                              |                             |                          |                             |                             |                              |
| >730 days              |                              |                             |                          |                             |                             |                              |
| Average                |                              |                             |                          |                             |                             |                              |
| Median                 |                              |                             |                          |                             |                             |                              |
| SD                     |                              |                             |                          |                             |                             |                              |
| Min                    |                              |                             |                          |                             |                             |                              |
| Max                    |                              |                             |                          |                             |                             |                              |

\*Calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**ILD-Table 2.3: Number of Index Drug Treatment Episodes and Number of Non-Index Study Drug Dispensed In Each Of The ILD-Broad Study Cohorts Before Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Drug Treatment Episodes</b>       | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|--------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| <b>Index Drug Treatment Episodes</b> |                              |                             |                          |                             |                             |                              |
| 1 Episode                            |                              |                             |                          |                             |                             |                              |
| 2 Episodes                           |                              |                             |                          |                             |                             |                              |
| 3 Episodes                           |                              |                             |                          |                             |                             |                              |
| 4+ Episodes                          |                              |                             |                          |                             |                             |                              |
| Average                              |                              |                             |                          |                             |                             |                              |
| Median                               |                              |                             |                          |                             |                             |                              |
| SD                                   |                              |                             |                          |                             |                             |                              |
| Min                                  |                              |                             |                          |                             |                             |                              |
| Max                                  |                              |                             |                          |                             |                             |                              |

**Number of Non-Index Study Drugs Dispensed Post Index Date**

1  
2  
3  
4

**ILD-Table 2.4: Baseline Characteristics Of Patients In The ILD-Broad Analysis Dataset After Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)*                               | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |

\* The list of baseline characteristic variables does not include all of the variables used for propensity score matching. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Table 2.5: Standardized Differences In PS Model Covariates Between ILD-Broad Dronedarone And Comparator Cohorts Before And After PS Matching: DoD Database – July 20, 2009 to September 30, 2014**

| Covariates                                                            | ILD Broad Study Cohorts Before PS Matching |    |    |    |                     |     |     | ILD Broad Analysis Dataset After PS Matching |     |     |     |                     |     |     |
|-----------------------------------------------------------------------|--------------------------------------------|----|----|----|---------------------|-----|-----|----------------------------------------------|-----|-----|-----|---------------------|-----|-----|
|                                                                       | Mean Value or %                            |    |    |    | 100*Difference / SD |     |     | Mean Value or %                              |     |     |     | 100*Difference / SD |     |     |
|                                                                       | MQ                                         | AM | SO | FL | iAM                 | iSO | iFL | mMQ                                          | mAM | mSO | mFL | iAM                 | iSO | iFL |
| Gender (% Female)                                                     |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Age on index date (mean)                                              |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Days from start of study to patient Index Date                        |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Asthma                                                                |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Bronchitis                                                            |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Chronic Obstructive Pulmonary Disease                                 |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Connective Tissue Disease                                             |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Exposure to Toxins                                                    |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Gastroesophageal Reflux Disease                                       |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Baseline use of other study medications                               |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Baseline use of other anti-arrhythmic medications                     |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Baseline use of agents associated with drug induced pulmonary disease |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Baseline use of therapeutic oxygen treatment                          |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Number of hospitalizations                                            |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Number of office visits                                               |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Number of ER visits                                                   |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Number of different medications                                       |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |
| Pulmonology specialty visits                                          |                                            |    |    |    |                     |     |     |                                              |     |     |     |                     |     |     |

MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Flecainide

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.



**ILD-Table 2.6: Follow-up Time For The ILD-Broad Analysis Dataset After Propensity Score Matching: DoD Database – July 20, 2009 to September 30, 2014**

| <b>Follow-up Time*</b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| 1 - 90 days            |                              |                             |                          |                             |
| 91 - 180 days          |                              |                             |                          |                             |
| 181 - 365 days         |                              |                             |                          |                             |
| 366 - 545 days         |                              |                             |                          |                             |
| 546 - 730 days         |                              |                             |                          |                             |
| >730 days              |                              |                             |                          |                             |
| Average                |                              |                             |                          |                             |
| Median                 |                              |                             |                          |                             |
| SD                     |                              |                             |                          |                             |
| Min                    |                              |                             |                          |                             |
| Max                    |                              |                             |                          |                             |

\*Calculated as time from Index Date through to the earliest of either end of eligibility, end of study or date of death. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Table 2.7: Numbers and Characteristics of Patients With Adjudicated ILD-Broad Outcome Events Identified During ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics*</b>                                  |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date*</b>               |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

\*Includes only "Yes" adjudicated outcome events. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

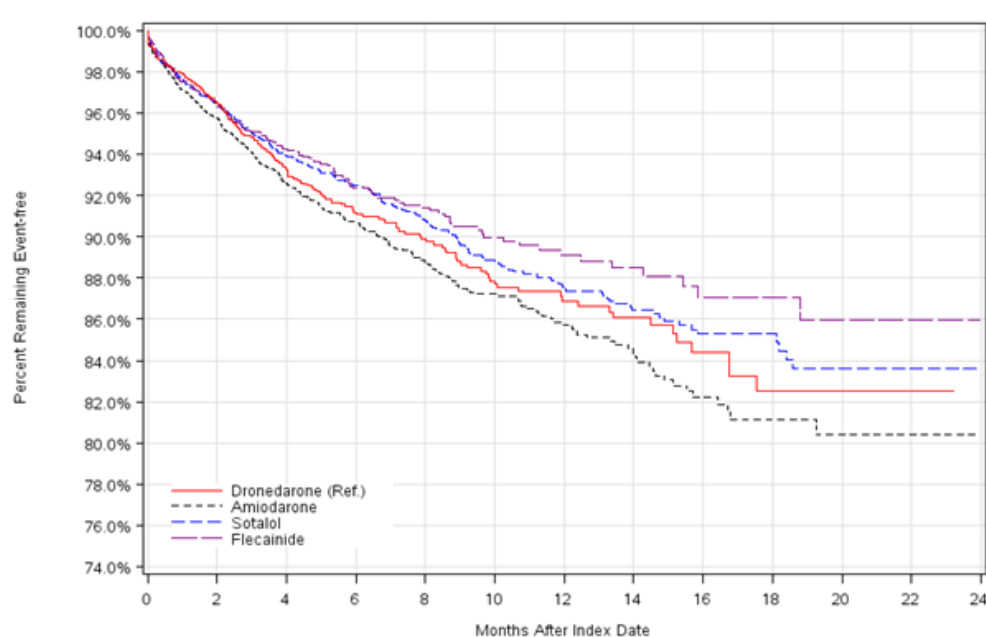
**ILD-Table 2.8: Incidence Rates (per 1000 person-years) and Hazard Ratio of Adjudicated ILD-Broad Outcome Events Identified during ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**

|                        | Dronedarone | Amiodarone | Sotalol | Flecainide |
|------------------------|-------------|------------|---------|------------|
| # Cases (Yes)          |             |            |         |            |
| # of Person-Years      |             |            |         |            |
| Incidence rate (95%CI) |             |            |         |            |
| Crude HR (95%CI)       | Reference   |            |         |            |
| Adjusted HR (95%CI)*   | Reference   |            |         |            |

\* Adjusted for ...

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Figure 2.1: Sample Kaplan Meier Survival Curve of ILD-Broad Adjudicated Events Identified During ILD Risk Period 1: DoD Database – July 20, 2009 to September 30, 2014**



**ILD-Table 2.9: Characteristics of Patients with Adjudicated ILD-Broad Outcome Events Identified during ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**

| Characteristics, N (%)                                | Dronedaron<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|---------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                     |                     |                  |                     |
| Yes                                                   |                     |                     |                  |                     |
| No                                                    |                     |                     |                  |                     |
| Indeterminate                                         |                     |                     |                  |                     |
| <b>Demographics*</b>                                  |                     |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                     |                     |                  |                     |
| 18-39 years                                           |                     |                     |                  |                     |
| 40-49 years                                           |                     |                     |                  |                     |
| 50-59 years                                           |                     |                     |                  |                     |
| 60-69 years                                           |                     |                     |                  |                     |
| 70-79 years                                           |                     |                     |                  |                     |
| 80+ years                                             |                     |                     |                  |                     |
| Gender (female)                                       |                     |                     |                  |                     |
| Race                                                  |                     |                     |                  |                     |
| White                                                 |                     |                     |                  |                     |
| Asian or Pacific Islander                             |                     |                     |                  |                     |
| Black                                                 |                     |                     |                  |                     |
| American Indian/Alaskan Native                        |                     |                     |                  |                     |
| Other                                                 |                     |                     |                  |                     |
| Unknown                                               |                     |                     |                  |                     |
| History of smoking                                    |                     |                     |                  |                     |
| <b>History of Disease</b>                             |                     |                     |                  |                     |
| Deyo-Charlson Index                                   |                     |                     |                  |                     |
| Asthma                                                |                     |                     |                  |                     |
| Bronchitis                                            |                     |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                     |                     |                  |                     |
| Connective Tissue Disease                             |                     |                     |                  |                     |
| Exposure to Toxins                                    |                     |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                     |                     |                  |                     |
| <b>History of Medication Use</b>                      |                     |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                     |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                     |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                     |                     |                  |                     |
| <b>Outcome Latency from Index Date*</b>               |                     |                     |                  |                     |
| Up to 1 month                                         |                     |                     |                  |                     |
| 1 Month up to 6 months                                |                     |                     |                  |                     |
| Greater than 6 months                                 |                     |                     |                  |                     |

\*Includes only "Yes" adjudicated outcome events. Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

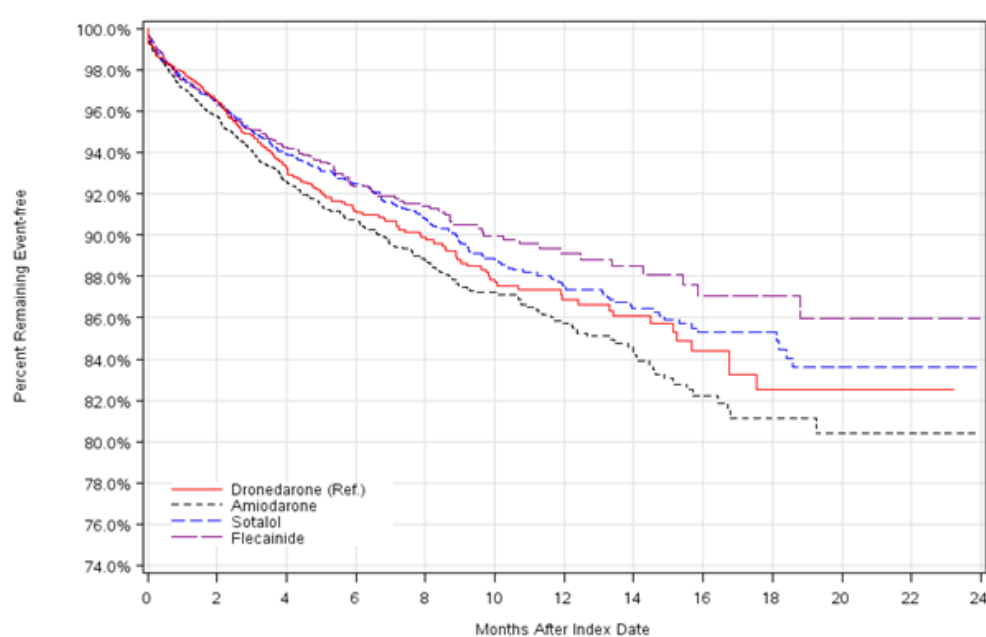
**ILD-Table 2.10: Incidence Rates (per 1000 person-years) and Hazard Ratio of Adjudicated ILD-Broad Outcome Events Identified during ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**

|                         | Dronedarone | Amiodarone | Sotalol | Flecainide |
|-------------------------|-------------|------------|---------|------------|
| # Cases (Yes)           |             |            |         |            |
| # of Person-Years       |             |            |         |            |
| Incidence rate (95% CI) |             |            |         |            |
| Crude HR (95% CI)       | Reference   |            |         |            |
| Adjusted HR (95% CI)*   | Reference   |            |         |            |

\* Adjusted for ...

Assumes Dofetilide and Propafenone cohorts do not meet the sample size requirement and are excluded from further analysis.

**ILD-Figure 2.2: Sample Kaplan Meier Survival Curve ILD-Broad Adjudicated Events Identified During ILD Risk Period 2: DoD Database – July 20, 2009 to September 30, 2014**



## **8 APPENDICES**

## APPENDIX A.1 STUDY DRUG COHORT DEFINITIONS

### 1) Dronedarone – Multaq

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00024414210 | MULTAQ      |
| 00024414218 | MULTAQ      |
| 00024414250 | MULTAQ      |
| 00024414260 | MULTAQ      |
| 21695092060 | MULTAQ      |
| 53360414200 | MULTAQ      |
| 54868308600 | MULTAQ      |

End.

### 2) Amiodarone – Cordarone, Cordarone IV, Pacerone

| NDC         | DESCRIPTION                        |
|-------------|------------------------------------|
| 00008081401 | CORDARONE IV                       |
| 00008418802 | CORDARONE                          |
| 00008418804 | CORDARONE                          |
| 00008418806 | CORDARONE                          |
| 00074434835 | AMIODARONE HCL                     |
| 00093913306 | AMIODARONE HCL                     |
| 00093913352 | AMIODARONE HCL                     |
| 00093913393 | AMIODARONE HCL                     |
| 00143987501 | AMIODARONE HCL INJECTION, SOLUTION |
| 00143987510 | AMIODARONE HYDROCHLORIDE           |
| 00185014405 | AMIODARONE HCL                     |
| 00185014409 | AMIODARONE HCL                     |
| 00185014460 | AMIODARONE HCL                     |
| 00185014490 | AMIODARONE HCL                     |
| 00245014001 | PACERONE                           |
| 00245014030 | PACERONE                           |
| 00245014401 | PACERONE                           |
| 00245014411 | PACERONE                           |
| 00245014430 | PACERONE                           |
| 00245014489 | PACERONE                           |
| 00245014501 | PACERONE                           |
| 00245014511 | PACERONE                           |
| 00245014515 | PACERONE                           |
| 00245014530 | PACERONE                           |
| 00245014589 | PACERONE                           |
| 00245014701 | PACERONE                           |
| 00245014715 | PACERONE                           |
| 00245014760 | PACERONE                           |
| 00245014789 | PACERONE                           |
| 00245014790 | PACERONE                           |
| 00409193302 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193303 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193401 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193411 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409434835 | AMIODARONE HYDROCHLORIDE           |
| 00409434849 | NOVAPLUS AMIODARONE HYDROCHLORIDE  |
| 00548138000 | AMIODARONE HCL INJECTION           |

|             |                                    |
|-------------|------------------------------------|
| 00548138100 | AMIODARONE HCL INJECTION           |
| 00548338000 | AMIODARONE HCL                     |
| 00555091704 | AMIODARONE HCL                     |
| 00555091709 | AMIODARONE HCL                     |
| 00615454505 | AMIODARONE HCL TABLET              |
| 00615454531 | AMIODARONE HCL TABLET              |
| 00615454539 | AMIODARONE HCL TABLET              |
| 00703133201 | AMIODARONE HCL                     |
| 00703133203 | AMIODARONE HYDROCHLORIDE           |
| 00703133501 | AMIODARONE HCL                     |
| 00703133601 | AMIODARONE HCL                     |
| 00781120305 | AMIODARONE HCL                     |
| 00781120360 | AMIODARONE HCL                     |
| 00781120392 | AMIODARONE HCL                     |
| 10019013101 | AMIODARONE HCL                     |
| 10019013301 | AMIODARONE HCL                     |
| 10019013302 | AMIODARONE HCL                     |
| 10019013304 | AMIODARONE HCL                     |
| 10019013313 | AMIODARONE HCL                     |
| 10019013319 | AMIODARONE HCL                     |
| 10019013389 | AMIODARONE HCL                     |
| 10139005003 | AMIODARONE HCL                     |
| 10139005009 | AMIODARONE HCL                     |
| 10139005010 | AMIODARONE HCL                     |
| 10139005011 | AMIODARONE HCL                     |
| 10139005028 | AMIODARONE HCL                     |
| 13107005605 | AMIODARONE HYDROCHLORIDE           |
| 13107005660 | AMIODARONE HYDROCHLORIDE           |
| 17236007560 | AMIODARONE HCL                     |
| 21695079630 | AMIODARONE HCL                     |
| 21695079660 | AMIODARONE HCL                     |
| 21695079690 | AMIODARONE HCL                     |
| 25021030266 | AMIODARONE HCL INJECTION, SOLUTION |
| 25021030273 | AMIODARONE HYDROCHLORIDE           |
| 35356000110 | AMIODARONE                         |
| 35356000190 | AMIODARONE HCL                     |
| 38245013325 | AMIODARONE HCL                     |
| 38245013355 | AMIODARONE HCL                     |
| 38245013368 | AMIODARONE HCL                     |
| 38779048605 | AMIODARONE HCL                     |
| 38779048608 | AMIODARONE HCL                     |
| 43066015010 | NEXTERONE                          |
| 43066015020 | NEXTERONE                          |
| 43066036020 | NEXTERONE INJECTION, SOLUTION      |
| 47463001360 | AMIODARONE HCL                     |
| 49349015402 | AMIODARONE HCL TABLET              |
| 49884045802 | AMIODARONE HCL                     |
| 49884045804 | AMIODARONE HCL                     |
| 49884045805 | AMIODARONE HCL                     |
| 51079090601 | AMIODARONE HCL                     |
| 51079090617 | AMIODARONE HYDROCHLORIDE           |
| 51079090619 | AMIODARONE HYDROCHLORIDE           |
| 51079090620 | AMIODARONE HCL                     |
| 51138049130 | AMIODARONE HCL                     |



|             |                                                 |
|-------------|-------------------------------------------------|
| 51672402503 | AMIODARONE HCL TABLET                           |
| 51672402504 | AMIODARONE HCL                                  |
| 51672405506 | AMIODARONE HCL TABLET                           |
| 51672405600 | AMIODARONE HCL TABLET                           |
| 51672405601 | AMIODARONE HCL TABLET                           |
| 51672405603 | AMIODARONE HCL TABLET                           |
| 51672405606 | AMIODARONE HCL TABLET                           |
| 51672405700 | AMIODARONE HCL                                  |
| 51672405706 | AMIODARONE HCL                                  |
| 51862015560 | AMIODARONE HCL TABLET                           |
| 51862015630 | AMIODARONE HCL TABLET                           |
| 51927376000 | AMIODARONE HYDROCHLORIDE                        |
| 52125099202 | AMIODARONE HCL TABLET                           |
| 52533010158 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52533010159 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584015303 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584034835 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 52584087501 | AMIODARONE HCL INJECTION                        |
| 53808106601 | AMIODARONE HCL TABLET                           |
| 54569176500 | CORDARONE                                       |
| 54569514000 | AMIODARONE HCL                                  |
| 54569514001 | AMIODARONE HCL                                  |
| 54569612900 | AMIODARONE HCL                                  |
| 54868461800 | AMIODARONE HCL                                  |
| 54868461801 | AMIODARONE HCL                                  |
| 54868461802 | AMIODARONE HCL                                  |
| 54868461803 | AMIODARONE HCL                                  |
| 54868518600 | PACERONE                                        |
| 54868572200 | AMIODARONE                                      |
| 55045286400 | AMIODARONE                                      |
| 55045286406 | AMIODARONE                                      |
| 55048001360 | AMIODARONE HCL                                  |
| 55154499600 | PACERONE                                        |
| 55154549200 | PACERONE                                        |
| 55154560600 | PACERONE                                        |
| 55390005701 | AMIODARONE HCL                                  |
| 55390005710 | AMIODARONE HCL                                  |
| 55390005810 | AMIODARONE HCL                                  |
| 55390009710 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 55390010501 | AMIODARONE HCL                                  |
| 55648073901 | AMIODARONE HCL INJECTION                        |
| 55648073902 | AMIODARONE HCL INJECTION                        |
| 55648073904 | AMIODARONE HCL INJECTION                        |
| 55648078001 | AMIODARONE HCL INJECTION                        |
| 55887079801 | AMIODARONE                                      |
| 55887079830 | AMIODARONE                                      |
| 55953021440 | AMIODARONE HCL                                  |
| 55953021441 | AMIODARONE HCL                                  |
| 55953021470 | AMIODARONE HCL                                  |
| 57315000901 | AMIODARONE HCL TABLET                           |
| 57315000902 | AMIODARONE HCL TABLET                           |
| 57315000904 | AMIODARONE HCL TABLET                           |
| 58016030400 | AMIODARONE                                      |
| 58016030430 | AMIODARONE                                      |

|             |                                                 |
|-------------|-------------------------------------------------|
| 58016030460 | AMIODARONE                                      |
| 58016030490 | AMIODARONE                                      |
| 60429024705 | AMIODARONE HCL                                  |
| 60429024760 | AMIODARONE HCL                                  |
| 60505072200 | AMIODARONE HCL                                  |
| 60505072201 | AMIODARONE HCL                                  |
| 60505265800 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265803 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265806 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265808 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 61703024103 | AMIODARONE HCL                                  |
| 61786030931 | AMIODARONE HCL TABLET                           |
| 62086015303 | AMIODARONE HCL                                  |
| 63323061603 | AMIODARONE HYDROCHLORIDE                        |
| 63323061609 | AMIODARONE HYDROCHLORIDE                        |
| 63323061613 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 63739038710 | AMIODARONE HYDROCHLORIDE                        |
| 64679073901 | AMIODARONE HCL INJECTION                        |
| 64679073902 | AMIODARONE HCL INJECTION                        |
| 64679078001 | AMIODARONE HCL INJECTION                        |
| 65084045618 | PACERONE                                        |
| 65084045620 | PACERONE                                        |
| 65841063105 | AMIODARONE HCL TABLET                           |
| 65841063106 | AMIODARONE HCL TABLET                           |
| 65841063110 | AMIODARONE HCL TABLET                           |
| 65841063114 | AMIODARONE HCL TABLET                           |
| 65841063130 | AMIODARONE HCL TABLET                           |
| 67457015300 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 67457015303 | AMIODARONE HCL                                  |
| 67457015309 | AMIODARONE HYDROCHLORIDE                        |
| 67457015318 | AMIODARONE HYDROCHLORIDE                        |
| 67544017630 | AMIODARONE HCL                                  |
| 67544057030 | PACERONE                                        |
| 68084037101 | AMIODARONE HYDROCHLORIDE                        |
| 68084037111 | AMIODARONE HCL                                  |
| 68382022705 | AMIODARONE HYDROCHLORIDE                        |
| 68382022706 | AMIODARONE HCL TABLET                           |
| 68382022710 | AMIODARONE HCL TABLET                           |
| 68382022714 | AMIODARONE HYDROCHLORIDE                        |
| 68382022730 | AMIODARONE HCL TABLET                           |
| 68382022777 | AMIODARONE HCL TABLET                           |
| 76237010830 | AMIODARONE HCL TABLET                           |

End.

3) **Sotalol** – Betapace, Betapace AF, Sorine, Sorine AF

| CODE        | DESCRIPTION    |
|-------------|----------------|
| 00093106001 | SOTALOL HCL    |
| 00093106101 | SOTALOL HCL    |
| 00093106201 | SOTALOL HCL    |
| 00093106301 | SOTALOL HCL    |
| 00093740106 | SOTALOL HCL AF |
| 00093740206 | SOTALOL HCL AF |
| 00093740306 | SOTALOL HCL AF |
| 00115271101 | SOTALOL HCL    |
| 00115271102 | SOTALOL HCL    |
| 00115271103 | SOTALOL HCL    |
| 00115272201 | SOTALOL HCL    |
| 00115272202 | SOTALOL HCL    |
| 00115272203 | SOTALOL HCL    |
| 00115273301 | SOTALOL HCL    |
| 00115273302 | SOTALOL HCL    |
| 00115273303 | SOTALOL HCL    |
| 00115274401 | SOTALOL HCL    |
| 00115274402 | SOTALOL HCL    |
| 00115274403 | SOTALOL HCL    |
| 00185017001 | SOTALOL HCL    |
| 00185017005 | SOTALOL HCL    |
| 00185017009 | SOTALOL HCL    |
| 00185017101 | SOTALOL HCL    |
| 00185017105 | SOTALOL HCL    |
| 00185017109 | SOTALOL HCL    |
| 00185017401 | SOTALOL HCL    |
| 00185017405 | SOTALOL HCL    |
| 00185017409 | SOTALOL HCL    |
| 00185017701 | SOTALOL HCL    |
| 00185017705 | SOTALOL HCL    |
| 00185017709 | SOTALOL HCL    |
| 00245001201 | SORINE         |
| 00245001211 | SORINE         |
| 00245001289 | SORINE         |
| 00245001301 | SORINE         |
| 00245001311 | SORINE         |
| 00245001389 | SORINE         |
| 00245001401 | SORINE         |
| 00245001411 | SORINE         |
| 00245001489 | SORINE         |
| 00245001501 | SORINE         |
| 00245001511 | SORINE         |
| 00245001589 | SORINE         |
| 00378030501 | SOTALOL HCL    |
| 00378031001 | SOTALOL HCL    |
| 00378031401 | SOTALOL HCL    |
| 00378512301 | SOTALOL HCL    |
| 00378512401 | SOTALOL HCL    |
| 00378512501 | SOTALOL HCL    |
| 00440836030 | SOTALOL HCL    |
| 00440836060 | SOTALOL HCL    |
| 00440836090 | SOTALOL HCL    |
| 00440836091 | SOTALOL HCL    |
| 00440836130 | SOTALOL HCL    |
| 00440836160 | SOTALOL HCL    |
| 00440836190 | SOTALOL HCL    |

|             |                   |
|-------------|-------------------|
| 00440836191 | SOTALOL HCL       |
| 00440836230 | SOTALOL HCL       |
| 00440836260 | SOTALOL HCL       |
| 00440836290 | SOTALOL HCL       |
| 00440836291 | SOTALOL HCL       |
| 00603576910 | SOTALOL HCL       |
| 00603576921 | SOTALOL HCL       |
| 00603576928 | SOTALOL HCL       |
| 00603576929 | SOTALOL HCL       |
| 00603576932 | SOTALOL HCL       |
| 00603577010 | SOTALOL HCL       |
| 00603577021 | SOTALOL HCL       |
| 00603577025 | SOTALOL HCL       |
| 00603577028 | SOTALOL HCL       |
| 00603577029 | SOTALOL HCL       |
| 00603577032 | SOTALOL HCL       |
| 00603577110 | SOTALOL HCL       |
| 00603577121 | SOTALOL HCL       |
| 00603577128 | SOTALOL HCL       |
| 00603577129 | SOTALOL HCL       |
| 00603577132 | SOTALOL HCL       |
| 00603577221 | SOTALOL HCL       |
| 00603577228 | SOTALOL HCL       |
| 00603577229 | SOTALOL HCL       |
| 00677170901 | SOTALOL HCL       |
| 00677170905 | SOTALOL HCL       |
| 00677170906 | SOTALOL HCL       |
| 00677170907 | SOTALOL HCL       |
| 00677171001 | SOTALOL HCL       |
| 00677171005 | SOTALOL HCL       |
| 00677171006 | SOTALOL HCL       |
| 00677171101 | SOTALOL HCL       |
| 00677171105 | SOTALOL HCL       |
| 00677171106 | SOTALOL HCL       |
| 00677171201 | SOTALOL HCL       |
| 00677171205 | SOTALOL HCL       |
| 00677171206 | SOTALOL HCL       |
| 00677171207 | SOTALOL HCL       |
| 00677189301 | SOTALOL HCL AF    |
| 00677189306 | SOTALOL HCL AF    |
| 00677189401 | SOTALOL HCL AF    |
| 00677189406 | SOTALOL HCL AF    |
| 00677189501 | SOTALOL HCL AF    |
| 00677189506 | SOTALOL HCL AF    |
| 15330020801 | SOTALOL HCL       |
| 15330020901 | SOTALOL HCL       |
| 15330021001 | SOTALOL HCL       |
| 21695039730 | SOTALOL           |
| 24338053025 | SOTYLIZE SOLUTION |
| 24338053048 | SOTYLIZE SOLUTION |
| 35356093530 | SOTALOL HCL       |
| 35356093560 | SOTALOL HCL       |
| 35356093590 | SOTALOL HCL       |
| 35356096430 | SOTALOL HCL       |
| 35356096460 | SOTALOL HCL       |
| 35356096490 | SOTALOL HCL       |
| 42291076001 | SOTALOL HCL       |
| 42291076101 | SOTALOL HCL       |
| 42291076201 | SOTALOL HCL       |

|             |                |
|-------------|----------------|
| 43063013330 | SOTALOL HCL    |
| 47463077830 | SOTALOL HCL AF |
| 47463077930 | SOTALOL HCL AF |
| 49884058201 | SOTALOL HCL    |
| 49884058210 | SOTALOL HCL    |
| 49884058301 | SOTALOL HCL    |
| 49884058310 | SOTALOL HCL    |
| 49884058401 | SOTALOL HCL    |
| 49884058410 | SOTALOL HCL    |
| 49884058501 | SOTALOL HCL    |
| 49884058510 | SOTALOL HCL    |
| 50419010510 | BETAPACE       |
| 50419010511 | BETAPACE       |
| 50419010610 | BETAPACE       |
| 50419010611 | BETAPACE       |
| 50419010710 | BETAPACE       |
| 50419010711 | BETAPACE       |
| 50419010910 | BETAPACE       |
| 50419010911 | BETAPACE       |
| 50419011506 | BETAPACE AF    |
| 50419011511 | BETAPACE AF    |
| 50419011606 | BETAPACE AF    |
| 50419011611 | BETAPACE AF    |
| 50419011906 | BETAPACE AF    |
| 50419011911 | BETAPACE AF    |
| 51138056130 | SOTALOL HCL    |
| 51138056230 | SOTALOL HCL    |
| 51138056330 | SOTALOL HCL    |
| 51138056430 | SOTALOL HCL    |
| 52544065401 | SOTALOL HCL    |
| 52544065501 | SOTALOL HCL    |
| 52544065601 | SOTALOL HCL    |
| 52544066501 | SOTALOL HCL    |
| 53217001190 | SOTALOL HCL    |
| 53489028801 | SOTALOL HCL    |
| 53489028802 | SOTALOL HCL    |
| 53489028803 | SOTALOL HCL    |
| 53489028805 | SOTALOL HCL    |
| 53489028810 | SOTALOL HCL    |
| 53489028901 | SOTALOL HCL    |
| 53489028902 | SOTALOL HCL    |
| 53489028903 | SOTALOL HCL    |
| 53489028905 | SOTALOL HCL    |
| 53489028910 | SOTALOL HCL    |
| 53489029001 | SOTALOL HCL    |
| 53489029002 | SOTALOL HCL    |
| 53489029003 | SOTALOL HCL    |
| 53489029005 | SOTALOL HCL    |
| 53489029010 | SOTALOL HCL    |
| 53489029101 | SOTALOL HCL    |
| 53489029102 | SOTALOL HCL    |
| 53489029103 | SOTALOL HCL    |
| 53489029105 | SOTALOL HCL    |
| 53489029110 | SOTALOL HCL    |
| 53489050301 | SOTALOL        |
| 53489050303 | SOTALOL        |
| 53489050305 | SOTALOL        |
| 53489050306 | SOTALOL        |
| 53489050307 | SOTALOL        |

|             |                |
|-------------|----------------|
| 53489050310 | SOTALOL        |
| 53489050401 | SOTALOL        |
| 53489050403 | SOTALOL        |
| 53489050405 | SOTALOL        |
| 53489050406 | SOTALOL        |
| 53489050407 | SOTALOL        |
| 53489050410 | SOTALOL        |
| 53489050501 | SOTALOL        |
| 53489050503 | SOTALOL        |
| 53489050505 | SOTALOL        |
| 53489050506 | SOTALOL        |
| 53489050507 | SOTALOL        |
| 53489050510 | SOTALOL        |
| 54569443400 | BETAPACE       |
| 54569443500 | BETAPACE       |
| 54868442300 | BETAPACE AF    |
| 54868442301 | BETAPACE AF    |
| 54868443500 | SOTALOL HCL    |
| 54868443501 | SOTALOL HCL    |
| 54868443502 | SOTALOL HCL    |
| 54868443503 | SOTALOL HCL    |
| 54868554900 | SOTALOL HCL    |
| 54868554901 | SOTALOL HCL    |
| 54868561400 | SOTALOL HCL    |
| 54868561401 | SOTALOL HCL AF |
| 55045316000 | SOTALOL HCL    |
| 55048077830 | SOTALOL HCL AF |
| 55048077930 | SOTALOL HCL AF |
| 57866903201 | SOTALOL HCL    |
| 57866903202 | SOTALOL HCL    |
| 57866903203 | SOTALOL HCL    |
| 57866903204 | SOTALOL HCL    |
| 57866903301 | SOTALOL HCL    |
| 57866903302 | SOTALOL HCL    |
| 57866903303 | SOTALOL HCL    |
| 57866903304 | SOTALOL HCL    |
| 57866903401 | SOTALOL HCL    |
| 57866903402 | SOTALOL HCL    |
| 57866903403 | SOTALOL HCL    |
| 57866903404 | SOTALOL HCL    |
| 58016018800 | SOTALOL HCL    |
| 58016018802 | SOTALOL HCL    |
| 58016018830 | SOTALOL HCL    |
| 58016018860 | SOTALOL HCL    |
| 58016018890 | SOTALOL HCL    |
| 60429039001 | SOTALOL HCL    |
| 60429039060 | SOTALOL HCL    |
| 60429039101 | SOTALOL HCL    |
| 60429039160 | SOTALOL HCL    |
| 60429039201 | SOTALOL HCL    |
| 60429039260 | SOTALOL HCL    |
| 60429074801 | SOTALOL HCL    |
| 60429074901 | SOTALOL HCL    |
| 60429075001 | SOTALOL HCL    |
| 60429075101 | SOTALOL HCL    |
| 60429094801 | SOTALOL HCL    |
| 60429094901 | SOTALOL HCL    |
| 60429095001 | SOTALOL HCL    |
| 60429095101 | SOTALOL HCL    |

|             |                |
|-------------|----------------|
| 60505008000 | SOTALOL HCL    |
| 60505008010 | SOTALOL HCL    |
| 60505008100 | SOTALOL HCL    |
| 60505008110 | SOTALOL HCL    |
| 60505008200 | SOTALOL HCL    |
| 60505008201 | SOTALOL HCL    |
| 60505015900 | SOTALOL HCL    |
| 60505022201 | SOTALOL HCL AF |
| 60505022210 | SOTALOL HCL    |
| 60505022220 | SOTALOL HCL    |
| 60505022301 | SOTALOL HCL AF |
| 60505022310 | SOTALOL HCL    |
| 60505022320 | SOTALOL HCL    |
| 60505022401 | SOTALOL HCL AF |
| 60505022410 | SOTALOL HCL    |
| 60505022420 | SOTALOL HCL    |
| 62451010510 | SOTALOL HCL    |
| 62451010610 | SOTALOL HCL    |
| 62451010710 | SOTALOL HCL    |
| 62451010910 | SOTALOL HCL    |
| 63629471910 | SOTALOL HCL    |
| 63629472010 | SOTALOL HCL    |
| 63629472020 | SOTALOL HCL    |
| 65162072510 | SOTALOL HCL    |
| 65162072710 | SOTALOL HCL    |
| 65162073110 | SOTALOL HCL    |
| 67457017610 | SOTALOL HCL    |
| 68084038701 | SOTALOL HCL    |
| 68084038711 | SOTALOL HCL    |
| 68084049701 | SOTALOL HCL    |
| 68084049711 | SOTALOL HCL    |
| 68084065401 | SOTALOL HCL    |
| 68084065411 | SOTALOL HCL    |
| 68115066100 | SOTALOL HCL    |
| 68151270290 | SOTALOL HCL    |

End.

4) **Flecainide** – Tambocor

| NDC         | DESCRIPTION        |
|-------------|--------------------|
| 00054001020 | FLECAINIDE ACETATE |
| 00054001021 | FLECAINIDE ACETATE |
| 00054001025 | FLECAINIDE ACETATE |
| 00054001120 | FLECAINIDE ACETATE |
| 00054001121 | FLECAINIDE ACETATE |
| 00054001125 | FLECAINIDE ACETATE |
| 00054001220 | FLECAINIDE ACETATE |
| 00054001221 | FLECAINIDE ACETATE |
| 00054001225 | FLECAINIDE ACETATE |
| 00089030510 | TAMBOCOR           |
| 00089030516 | TAMBOCOR           |
| 00089030710 | TAMBOCOR           |
| 00089030716 | TAMBOCOR           |
| 00089031410 | TAMBOCOR           |
| 00089031416 | TAMBOCOR           |
| 00378850501 | FLECAINIDE ACETATE |
| 00378851001 | FLECAINIDE ACETATE |
| 00378851501 | FLECAINIDE ACETATE |
| 00440754260 | FLECAINIDE ACETATE |
| 00440754360 | FLECAINIDE ACETATE |
| 00440754460 | FLECAINIDE ACETATE |
| 00555085902 | FLECAINIDE ACETATE |
| 00555086002 | FLECAINIDE ACETATE |
| 00555086102 | FLECAINIDE ACETATE |
| 00781506201 | FLECAINIDE ACETATE |
| 00781506301 | FLECAINIDE ACETATE |
| 00781506401 | FLECAINIDE ACETATE |
| 12280018230 | TAMBOCOR           |
| 29336030510 | TAMBOCOR           |
| 29336030710 | TAMBOCOR           |
| 29336031410 | TAMBOCOR           |
| 29366031410 | TAMBOCOR           |
| 49884069401 | FLECAINIDE ACETATE |
| 49884069501 | FLECAINIDE ACETATE |
| 49884069601 | FLECAINIDE ACETATE |
| 50268032011 | FLECAINIDE ACETATE |
| 50268032015 | FLECAINIDE ACETATE |
| 50268032111 | FLECAINIDE ACETATE |
| 50268032115 | FLECAINIDE ACETATE |
| 50268032211 | FLECAINIDE ACETATE |
| 50268032215 | FLECAINIDE ACETATE |
| 51079098701 | FLECAINIDE ACETATE |
| 51079098720 | FLECAINIDE ACETATE |
| 51079098820 | FLECAINIDE ACETATE |
| 54569050000 | TAMBOCOR           |
| 54569613100 | FLECAINIDE ACETATE |
| 54569613200 | FLECAINIDE ACETATE |
| 54868440700 | TAMBOCOR           |
| 54868506500 | TAMBOCOR           |
| 54868506501 | TAMBOCOR           |
| 54868507400 | FLECAINIDE ACETATE |
| 54868507401 | FLECAINIDE ACETATE |
| 54868507402 | FLECAINIDE ACETATE |
| 54868507403 | FLECAINIDE ACETATE |
| 54868540500 | FLECAINIDE ACETATE |
| 54868540501 | FLECAINIDE ACETATE |



|             |                    |
|-------------|--------------------|
| 54868558600 | FLECAINIDE         |
| 54868558601 | FLECAINIDE ACETATE |
| 55045381901 | FLECAINIDE ACETATE |
| 58016096202 | FLECAINIDE ACETATE |
| 58016096203 | FLECAINIDE ACETATE |
| 58016096204 | FLECAINIDE ACETATE |
| 58016096230 | FLECAINIDE ACETATE |
| 58016096240 | FLECAINIDE ACETATE |
| 58016096256 | FLECAINIDE ACETATE |
| 58016096260 | FLECAINIDE ACETATE |
| 58016096290 | FLECAINIDE ACETATE |
| 60505266000 | FLECAINIDE ACETATE |
| 60505266001 | FLECAINIDE ACETATE |
| 60505266003 | FLECAINIDE ACETATE |
| 60505266005 | FLECAINIDE ACETATE |
| 60505266008 | FLECAINIDE ACETATE |
| 60505266100 | FLECAINIDE ACETATE |
| 60505266101 | FLECAINIDE ACETATE |
| 60505266103 | FLECAINIDE ACETATE |
| 60505266105 | FLECAINIDE ACETATE |
| 60505266108 | FLECAINIDE ACETATE |
| 60505266200 | FLECAINIDE ACETATE |
| 60505266201 | FLECAINIDE ACETATE |
| 60505266203 | FLECAINIDE ACETATE |
| 60505266205 | FLECAINIDE ACETATE |
| 63304079401 | FLECAINIDE ACETATE |
| 63304079501 | FLECAINIDE ACETATE |
| 63304079601 | FLECAINIDE ACETATE |
| 65162064110 | FLECAINIDE ACETATE |
| 65162064111 | FLECAINIDE ACETATE |
| 65162064210 | FLECAINIDE ACETATE |
| 65162064211 | FLECAINIDE ACETATE |
| 65162064310 | FLECAINIDE ACETATE |
| 65162064311 | FLECAINIDE ACETATE |
| 66105015202 | TAMBOCOR           |
| 66105015203 | TAMBOCOR           |
| 66105015206 | TAMBOCOR           |
| 66105015209 | TAMBOCOR           |
| 66105015210 | TAMBOCOR           |
| 68084054011 | FLECAINIDE ACETATE |
| 68084054021 | FLECAINIDE ACETATE |
| 68151146402 | FLECAINIDE ACETATE |
| 99207018050 | TAMBOCOR           |
| 99207018110 | TAMBOCOR           |
| 99207018215 | TAMBOCOR           |

End.

5) **Dofetilide** – Tikosyn

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00069580043 | TIKOSYN     |
| 00069580060 | TIKOSYN     |
| 00069580061 | TIKOSYN     |
| 00069581043 | TIKOSYN     |
| 00069581060 | TIKOSYN     |
| 00069581061 | TIKOSYN     |
| 00069582043 | TIKOSYN     |
| 00069582060 | TIKOSYN     |
| 00069582061 | TIKOSYN     |

End.

6) **Propafenone** – Rythmol, Rythmol SR

| NDC         | DESCRIPTION              |
|-------------|--------------------------|
| 00044502202 | RYTHMOL                  |
| 00044502210 | RYTHMOL                  |
| 00044502302 | RYTHMOL                  |
| 00044502310 | RYTHMOL                  |
| 00044502402 | RYTHMOL                  |
| 00044502410 | RYTHMOL                  |
| 00074162812 | RYTHMOL                  |
| 00074162814 | RYTHMOL                  |
| 00074173212 | RYTHMOL                  |
| 00074173214 | RYTHMOL                  |
| 00074183112 | RYTHMOL                  |
| 00074183114 | RYTHMOL                  |
| 00173078601 | RYTHMOL SR               |
| 00173078801 | RYTHMOL SR               |
| 00173078901 | RYTHMOL SR               |
| 00173079220 | RYTHMOL                  |
| 00173079420 | RYTHMOL                  |
| 00173082318 | RYTHMOL SR               |
| 00173082418 | RYTHMOL SR               |
| 00173082618 | RYTHMOL SR               |
| 00591058201 | PROPAFENONE HCL          |
| 00591058301 | PROPAFENONE HCL          |
| 00603544810 | PROPAFENONE, FILM COATED |
| 00603544821 | PROPAFENONE HCL          |
| 00603544825 | PROPAFENONE HCL          |
| 00603544828 | PROPAFENONE, FILM COATED |
| 00603544832 | PROPAFENONE, FILM COATED |
| 00603544910 | PROPAFENONE, FILM COATED |
| 00603544921 | PROPAFENONE HCL          |
| 00603544925 | PROPAFENONE, FILM COATED |
| 00603544928 | PROPAFENONE, FILM COATED |
| 00603544932 | PROPAFENONE, FILM COATED |
| 00603545010 | PROPAFENONE, FILM COATED |
| 00603545021 | PROPAFENONE HCL          |
| 00603545028 | PROPAFENONE, FILM COATED |
| 00603545032 | PROPAFENONE, FILM COATED |
| 00615757439 | PROPAFENONE, FILM COATED |
| 00677181501 | PROPAFENONE HCL          |
| 00677181503 | PROPAFENONE HCL          |
| 00677181505 | PROPAFENONE HCL          |
| 00677181601 | PROPAFENONE HCL          |
| 00677181603 | PROPAFENONE HCL          |

|             |                               |
|-------------|-------------------------------|
| 00677181605 | PROPAFENONE HCL               |
| 00677181701 | PROPAFENONE HCL               |
| 00677181703 | PROPAFENONE HCL               |
| 00677181705 | PROPAFENONE HCL               |
| 05515509500 | PROPAFENONE, FILM COATED      |
| 21695081460 | PROPAFENONE HCL ER            |
| 49884009901 | PROPAFENONE, EXTENDED RELEASE |
| 49884009902 | PROPAFENONE HCL ER            |
| 49884009905 | PROPAFENONE HCL ER            |
| 49884009909 | PROPAFENONE HCL ER            |
| 49884009910 | PROPAFENONE, EXTENDED RELEASE |
| 49884011301 | PROPAFENONE, EXTENDED RELEASE |
| 49884011302 | PROPAFENONE, EXTENDED RELEASE |
| 49884011305 | PROPAFENONE, EXTENDED RELEASE |
| 49884011309 | PROPAFENONE, EXTENDED RELEASE |
| 49884011310 | PROPAFENONE, EXTENDED RELEASE |
| 49884020902 | PROPAFENONE HCL ER            |
| 49884020905 | PROPAFENONE HCL ER            |
| 49884020909 | PROPAFENONE HCL ER            |
| 49884021001 | PROPAFENONE, EXTENDED RELEASE |
| 49884021002 | PROPAFENONE HCL ER            |
| 49884021005 | PROPAFENONE HCL ER            |
| 49884021009 | PROPAFENONE HCL ER            |
| 49884021010 | PROPAFENONE, EXTENDED RELEASE |
| 49884021101 | PROPAFENONE, EXTENDED RELEASE |
| 49884021102 | PROPAFENONE HCL ER            |
| 49884021105 | PROPAFENONE HCL ER            |
| 49884021109 | PROPAFENONE HCL ER            |
| 49884021110 | PROPAFENONE, EXTENDED RELEASE |
| 50111070801 | PROPAFENONE HCL               |
| 50111070901 | PROPAFENONE HCL               |
| 50111071001 | PROPAFENONE HCL               |
| 51079099601 | PROPAFENONE HCL               |
| 51079099620 | PROPAFENONE HCL               |
| 52544058201 | PROPAFENONE HCL               |
| 52544058301 | PROPAFENONE HCL               |
| 53489055101 | PROPAFENONE HCL               |
| 53489055103 | PROPAFENONE HCL               |
| 53489055105 | PROPAFENONE HCL               |
| 53489055107 | PROPAFENONE, FILM COATED      |
| 53489055110 | PROPAFENONE, FILM COATED      |
| 53489055201 | PROPAFENONE HCL               |
| 53489055203 | PROPAFENONE HCL               |
| 53489055205 | PROPAFENONE HCL               |
| 53489055207 | PROPAFENONE, FILM COATED      |
| 53489055210 | PROPAFENONE, FILM COATED      |
| 53489055301 | PROPAFENONE HCL               |
| 53489055303 | PROPAFENONE HCL               |
| 53489055305 | PROPAFENONE HCL               |
| 53489055307 | PROPAFENONE, FILM COATED      |
| 53489055310 | PROPAFENONE, FILM COATED      |
| 54569613300 | PROPAFENONE HCL               |
| 54868477000 | PROPAFENONE HCL               |
| 54868477001 | PROPAFENONE HYDROCHLORIDE     |
| 54868477002 | PROPAFENONE HYDROCHLORIDE     |
| 54868477003 | PROPAFENONE HCL               |
| 54868477004 | PROPAFENONE HYDROCHLORIDE     |
| 54868477005 | PROPAFENONE HYDROCHLORIDE     |
| 54868595000 | PROPAFENONE HCL               |

|             |                           |
|-------------|---------------------------|
| 54868595001 | PROPAFENONE HCL           |
| 54868595002 | PROPAFENONE, FILM COATED  |
| 58016030300 | PROPAFENONE               |
| 58016030330 | PROPAFENONE               |
| 58016030360 | PROPAFENONE               |
| 58016030390 | PROPAFENONE               |
| 58177033104 | PROPAFENONE HCL           |
| 58177033111 | PROPAFENONE HCL           |
| 58177033112 | PROPAFENONE HCL           |
| 58177033204 | PROPAFENONE HCL           |
| 58177033304 | PROPAFENONE HCL           |
| 62559023001 | PROPAFENONE, FILM COATED  |
| 62559023101 | PROPAFENONE, FILM COATED  |
| 62559023201 | PROPAFENONE, FILM COATED  |
| 63629386901 | PROPAFENONE HCL           |
| 63739050910 | PROPAFENONE, FILM COATED  |
| 63739051010 | PROPAFENONE, FILM COATED  |
| 65726026115 | RYTHMOL SR                |
| 65726026125 | RYTHMOL SR                |
| 65726026190 | RYTHMOL SR                |
| 65726026215 | RYTHMOL SR                |
| 65726026225 | RYTHMOL SR                |
| 65726026290 | RYTHMOL SR                |
| 65726026315 | RYTHMOL SR                |
| 65726026325 | RYTHMOL SR                |
| 65726026390 | RYTHMOL SR                |
| 65726026525 | RYTHMOL                   |
| 65726026590 | RYTHMOL                   |
| 65726026625 | RYTHMOL                   |
| 65726026690 | RYTHMOL                   |
| 65726026725 | RYTHMOL                   |
| 65726026790 | RYTHMOL                   |
| 66993011460 | PROPAFENONE SR            |
| 66993011560 | PROPAFENONE SR            |
| 66993011660 | PROPAFENONE SR            |
| 68084036101 | PROPAFENONE HYDROCHLORIDE |
| 68084036111 | PROPAFENONE HCL           |
| 68084085832 | PROPAFENONE ER            |
| 68084085833 | PROPAFENONE ER            |
| 68084091732 | PROPAFENONE ER            |
| 68084091733 | PROPAFENONE ER            |

End.

## APPENDIX A.2 EXCLUSIONARY CONDITIONS DEFINITIONS

### History of Cancer

#### ICD-9-CM Diagnosis Range

140 – 209.xx Cancer

V10.x Personal history of malignant neoplasms

### History of Organ Transplant

#### ICD-9-CM Diagnoses

996.81 Complications of a transplanted kidney  
996.82 Complications of a transplanted liver  
996.83 Complications of a transplanted heart  
996.84 Complications of a transplanted lung  
996.86 Complications of a transplanted pancreas  
V42.0x Transplant – Kidney, status post  
V42.1x Transplant – Heart  
V42.6x Transplant – Lung  
V42.7x Transplant – Liver  
V42.83 Pancreas replaced by transplant

#### ICD-9-CM Procedures

33.5 Lung transplant  
33.50 Lung transplantation, not otherwise specified  
33.51 Unilateral lung transplantation  
33.52 Bilateral lung transplantation  
33.6 Combined heart-lung transplantation  
37.51 Heart transplantation  
37.55 Removal of internal biventricular heart replacement system  
~~50.11 Closed (percutaneous) [needle] biopsy of liver~~  
~~50.12 Open biopsy of liver~~  
~~50.13 Transjugular liver biopsy~~  
~~50.14 Laparoscopic liver biopsy~~  
50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver  
50.91 Percutaneous aspiration of liver  
52.8 Transplant of pancreas  
52.80 Pancreatic transplant, not otherwise specified  
52.81 Reimplantation of pancreatic tissue  
52.82 Homotransplant of pancreas  
52.83 Heterotransplant of pancreas  
52.84 Autotransplantation of cells of islets of langerhans  
52.85 Allotransplantation of cells of islets of langerhans  
52.86 Transplantation of cells of islets of langerhans, not otherwise specified  
55.53 Removal transplant/rejected kidney  
55.69 Other kidney transplantation

#### CPT® Procedures

32851 Lung transplant, single; without cardiopulmonary bypass  
32852 Lung transplant, single; with cardiopulmonary bypass

- 32853 Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
- 32854 Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
- 33935 Heart-lung transplant with recipient cardiectomy-pneumonectomy
- 33945 Heart transplant, with or without recipient cardiectomy
- 47135 Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
- 47136 Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age
- 48160 Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
- 48554 Transplantation of pancreatic allograft
- 48556 Removal of transplanted pancreatic allograft
- 50360 Renal allotransplantation, implantation of graft; without recipient nephrectomy
- 50365 Renal allotransplantation, implantation of graft; with recipient nephrectomy
- 50370 Removal of transplanted renal allograft
- 50380 Renal autotransplantation, reimplantation of kidney

## History of HIV

### ICD-9-CM Diagnosis

- 042 Human immunodeficiency virus (HIV) disease

## History of Pregnancy (Index date minus 280 days, through index date minus 1)

### ICD-9-CM Diagnoses

- V22 Normal pregnancy
- V22.0 Supervision of normal first pregnancy
- V22.1 Supervision of other normal pregnancy
- V22.2 Pregnant state incidental
- V23 Supervision of high-risk pregnancy
- V23.0 Supervision of high-risk pregnancy with history of infertility
- V23.1 Supervision of high-risk pregnancy with history of trophoblastic disease
- V23.2 Supervision of high-risk pregnancy with history of abortion
- V23.3 Supervision of high-risk pregnancy with grand multiparity
- V23.4 Supervision of high-risk pregnancy with other poor obstetric history
- V23.41 Supervision of high-risk pregnancy with history of pre-term labor
- V23.42 Supervision of high-risk pregnancy with history of ectopic pregnancy
- V23.49 Supervision of high-risk pregnancy with other poor obstetric history
- V23.5 Supervision of high-risk pregnancy with other poor reproductive history
- V23.7 Supervision of high-risk pregnancy with insufficient prenatal care
- V23.8 Supervision of other high-risk pregnancy
- V23.81 Supervision of high-risk pregnancy with elderly primigravida
- V23.82 Supervision of high-risk pregnancy with elderly multigravida
- V23.83 Supervision of high-risk pregnancy with young primigravida
- V23.84 Supervision of high-risk pregnancy with young multigravida
- V23.85 Supervision of high-risk pregnancy resulting from assisted reproductive technology
- V23.86 Supervision of high-risk pregnancy with history of in utero procedure during previous pregnancy
- V23.87 Supervision of high-risk pregnancy with inconclusive fetal viability
- V23.89 Supervision of other high-risk pregnancy
- V23.9 Supervision of unspecified high-risk pregnancy
- V28 Encounter for antenatal screening of mother
- V28.0 Screening for chromosomal anomalies by amniocentesis
- V28.1 Screening for raised alpha-fetoprotein levels in amniotic fluid
- V28.2 Other antenatal screening based on amniocentesis
- V28.3 Encounter for routine screening for malformation using ultrasonics
- V28.4 Antenatal screening for fetal growth retardation using ultrasonics

- V28.5 Antenatal screening for isoimmunization
- V28.6 Antenatal screening for streptococcus b
- V28.8 Other specified antenatal screening
- V28.81 Encounter for fetal anatomic survey
- V28.82 Encounter for screening for risk of preterm labor
- V28.89 Other specified antenatal screening
- V28.9 Unspecified antenatal screening

**ICD-9-CM Procedures**

- 72 Forceps, vacuum, and breech delivery
- 72.0 Low forceps operation
- 72.1 Low forceps operation with episiotomy
- 72.2 Mid forceps operation
- 72.21 Mid forceps operation with episiotomy
- 72.29 Other mid forceps operation
- 72.3 High forceps operation
- 72.31 High forceps operation with episiotomy
- 72.39 Other high forceps operation
- 72.4 Forceps rotation of fetal head
- 72.5 Breech extraction
- 72.51 Partial breech extraction with forceps to aftercoming head
- 72.52 Other partial breech extraction
- 72.53 Total breech extraction with forceps to aftercoming head
- 72.54 Other total breech extraction
- 72.6 Forceps application to aftercoming head
- 72.7 Vacuum extraction
- 72.71 Vacuum extraction with episiotomy
- 72.79 Other vacuum extraction
- 72.8 Other specified instrumental delivery
- 72.9 Unspecified instrumental delivery
- 73 Other procedures inducing or assisting delivery
- 73.0 Artificial rupture of membranes
- 73.01 Induction of labor by artificial rupture of membranes
- 73.09 Other artificial rupture of membranes
- 73.1 Other surgical induction of labor
- 73.2 Internal and combined version and extraction
- 73.21 Internal and combined version without extraction
- 73.22 Internal and combined version with extraction
- 73.3 Failed forceps
- 73.4 Medical induction of labor
- 73.5 Manually assisted delivery
- 73.51 Manual rotation of fetal head
- 73.59 Other manually assisted delivery
- 73.6 Episiotomy
- 73.8 Operations on fetus to facilitate delivery
- 73.9 Other operations assisting delivery
- 73.91 External version assisting delivery
- 73.92 Replacement of prolapsed umbilical cord
- 73.93 Incision of cervix to assist delivery
- 73.94 Pubiotomy to assist delivery
- 73.99 Other operations assisting delivery
- 74 Cesarean section and removal of fetus
- 74.0 Classical cesarean section
- 74.1 Low cervical cesarean section
- 74.2 Extraperitoneal cesarean section
- 74.3 Removal of extratubal ectopic pregnancy
- 74.4 Cesarean section of other specified type
- 74.9 Cesarean section of unspecified type
- 74.91 Hysterotomy to terminate pregnancy
- 74.99 Other cesarean section of unspecified type
- 75 Other obstetric operations
- 75.0 Intra-amniotic injection for abortion

- 75.1 Diagnostic amniocentesis
- 75.2 Intrauterine transfusion
- 75.3 Other intrauterine operations on fetus and amnion
- 75.31 Amnioscopy
- 75.32 Fetal ekg (scalp)
- 75.33 Fetal blood sampling and biopsy
- 75.34 Other fetal monitoring
- 75.35 Other diagnostic procedures on fetus and amnion
- 75.36 Correction of fetal defect
- 75.37 Amnioinfusion
- 75.38 Fetal pulse oximetry

### **CPT® Procedures**

- 59120 Tx ectopic pregnancy abdominal/vaginal appr
- 59121 Tx ectopic pregnancy w/o salping&/oophorectomy
- 59130 Tx ectopic pregnancy abdl pregnancy
- 59135 Tx ectopic pregnancy ntrstl req tot hyst
- 59136 Tx ectopic pregnancy ntrstl prtl rescj uter
- 59140 Tx ectopic pregnancy cervical w/evacuation
- 59150 Laps tx ectopic preg w/o salping&/oophorectomy
- 59151 Laps tx ectopic preg w/salping&/oophorectomy
- 59160 Curettage postpartum
- 59200 Insertion cervical dilator separate procedure
- 59300 Episiotomy/vag rpr oth/thn attending
- 59320 Cerclage cervix pregnancy vaginal
- 59325 Cerclage cervix pregnancy abdominal
- 59350 Hysterorrhaphy ruptured uterus
- 59400 Ob care antepartum vag dlvr & postpartum
- 59409 Vaginal delivery only
- 59410 Vaginal delivery only w/postpartum care
- 59412 External cephalic version w/wo tocolysis
- 59414 Delivery placenta separate procedure
- 59425 Antepartum care only 4-6 visits
- 59426 Antepartum care only 7/> visits
- 59430 Postpartum care only separate procedure
- 59510 Ob antepartum care cesarean dlvr & postpartum
- 59514 Cesarean delivery only
- 59515 Cesarean delivery only w/postpartum care
- 59525 Stot/tot hysterectomy after cesaren delivery
- 59610 Routine ob care vag dlvr & postpartum care vb
- 59612 Vaginal delivery after cesarean delivery
- 59614 Vaginal delivery & postpartum care vbac
- 59618 Routine obstetrical care attempted vbac
- 59620 Cesarean delivery attempted vbac
- 59622 Cesarean dlvr & postpartum care attempted vba
- 59812 Tx incomplete abortion any trimester surgical
- 59820 Tx missed abortion first trimester surgical
- 59821 Tx missed abortion second trimester surgical
- 59830 Tx septic abortion surgical
- 59840 Induced abortion dilation and curettage
- 59841 Induced abortion dilation & evaucation
- 59850 Induced abortion 1/> amniotic injx w/d&c/evacj
- 59851 Induce abort 1/> amniot njxs dlvr fetus d&c
- 59852 Induce abort 1/> amniot njxs dlvr fetus hystotm
- 59855 Induced abort 1/> vag suppositories dlvr fetus
- 59856 Induced abort 1/> vag supp dlvr fetus d&c &/evac
- 59857 Induced abort 1/> vag suppos dlvr fetus hystot
- 59866 Multifetal pregnancy reduction
- 59870 Uterine evacuation & curettage hydatidiform mole
- 59871 Removal cerclage suture under anesthesia
- 59897 Unlisted fetal invasive px w/ultrasound
- 59898 Unlisted laparoscopy px maternity care&delivery



59899 Unlisted procedure maternity care & delivery  
 76801 Us pregnant uterus 14 wk transabdl 1/1st gestat  
 76802 Us preg uterus 14 wk transabdl each gestation  
 76805 Us preg uterus after 1st trimest 1/1st gestation  
 76810 Us preg uterus > 1st trimester abdl ea gestatio  
 76811 Us preg uterus w/detail fetal anat 1st gestation  
 76812 Us preg uterus detail fetal anat exam ea gestat  
 76813 Us fetal nuchal translucency 1st gestation  
 76814 Us fetal nuchal translucency ea addl gestation  
 76815 Us pregnant uterus limited 1/> fetuses  
 76816 Us preg uterus real time f/u trnsabdl per fetus  
 76817 Us preg uterus real time w/image dcmtn transvag

## History of Pregnancy (Index Date plus 280 days)

### ICD-9-CM Diagnoses

631 – 639.xx Ectopic and molar pregnancy and other pregnancy with abortive outcomes  
 640 – 649.xx Complications mainly related to pregnancy  
 650 – 659.xx Normal delivery, and other indications for care in pregnancy, labor, and delivery  
 660 – 669.xx Complications occurring mainly in the course of labor and delivery  
 670 – 677.xx Complications of the puerperium  
 678 – 679.xx Other maternal and fetal complications  
 V202 Routine Infant/Child Health Check  
 V203 Newborn Health Supervision  
 V2031 Health Supervision Nb <8 Days  
 V2032 Health Supervision Nb 8-28 Days  
 V213 Low Birth Weight Status  
 V2130 Low Birth Weight Unspec  
 V2131 Low Birth Weight <500 Gm  
 V2132 Low Birth Weight 500-999gm  
 V2133 Low Birth Weight 1000-1499gm  
 V2134 Low Birth Weight 1500-1999gm  
 V2135 Low Birth Weight 2000-2500gm  
 V218 Other Constit State In Development  
 V219 Unspec Constit State In Developmnt  
 V24 Postpartum Care And Examination  
 V240 Postpartum Care Exam After Delivery  
 V241 Postpartum Care Lactating Mother  
 V27 Outcome Of Delivery  
 V270 Deliver Single Liveborn  
 V271 Deliver Single Stillborn  
 V272 Deliver Twins Liveborn  
 V273 Delivery Twins One Stillborn  
 V274 Delivery Twins Both Stillborn  
 V275 Delivery Mult Birth All Liveborn  
 V276 Delivery Mult Birth Some Liveborn  
 V277 Delivery Mult Birth All Stillborn  
 V279 Outcome Of Delivery Unspec  
 V29 Observ Suspect Problem Newborn  
 V290 Infant Observation Infectious  
 V291 Infant Observation Neurology  
 V292 Infant Observation Respirat  
 V293 Infant Obser Genetic Cond  
 V298 Infant Observatn Cond Ot  
 V299 Infant Observatn Cond Unspec  
 V30 Single Liveborn  
 V300 Single Liveborn Born In Hospital  
 V3000 Sgl Liveborn No C-Section  
 V3001 Sgl Liveborn W C-Section  
 V301 Sgl Livebrn Before Admission  
 V302 Sgl Liveborn Not Admitted

|       |                                   |
|-------|-----------------------------------|
| V31   | Twin Birth Mate Liveborn          |
| V310  | Twin Birth Mate Lb In Hospital    |
| V3100 | Twin Mate In Hospital             |
| V3101 | Twin Mate C-Section               |
| V311  | Twin Mate Before Admission        |
| V312  | Twin Mate Not Admitted            |
| V32   | Twin Birth Mate Stillborn         |
| V320  | Twin Birth Mate Sb In Hospital    |
| V3200 | Twin Mate Stillborn In Hosp       |
| V3201 | Twin Mate Stillbrn C-Section      |
| V321  | Twin Mate Stillborn Before Adm    |
| V322  | Twin Mate Stillborn Not Admit     |
| V33   | Twin Birth Unspecified            |
| V330  | Twin Unsp In Hospital             |
| V3300 | Twin Unsp In Hospital             |
| V3301 | Twin Unsp C-Section               |
| V331  | Twin Unsp Before Admission        |
| V332  | Twin Unsp Not Admitted            |
| V34   | Ot Multiple In Hospital           |
| V340  | Ot Multiple Birth                 |
| V3400 | Ot Multiple In Hospital           |
| V3401 | Ot Multiple C-Section             |
| V341  | Ot Multiple Before Adm            |
| V342  | Ot Multiple Not Admitted          |
| V35   | Ot Multiple Stillborn             |
| V350  | Ot Multiple Stillborn In Hosp     |
| V3500 | Ot Multiple Stillborn In Hosp     |
| V3501 | Ot Multiple Stillborn C-Section   |
| V351  | Ot Multiple Stillborn Before Adm  |
| V352  | Ot Multiple Stillborn Not Adm     |
| V36   | Multiple Live/Still Unspecified   |
| V360  | Multip Live/Still Born In Hosptal |
| V3600 | Multiple Live/Still In Hosptal Ot |
| V3601 | Multiple Live/Still By C-Section  |
| V361  | Multiple Live/Still Before Adm    |
| V362  | Multiple Live/Still Not Admitted  |
| V37   | Unspecified Multiple Birth        |
| V370  | Unspecified Multiple Birth No C-S |
| V3700 | Multiple Nb Unsp In Hosp Ot       |
| V3701 | Multiple Nb Unsp C-Section        |
| V371  | Multiple Brth Unsp Before Adm     |
| V372  | Multiple Birth Unsp Not Admit     |
| V39   | Liveborn Unspecified              |
| V390  | Liveborn In Hospital              |
| V3900 | Liveborn Unsp In Hosp             |
| V3901 | Liveborn Unsp C-Section           |
| V391  | Liveborn Unsp Before Adm          |
| V392  | Liveborn Unsp Not Admitted        |

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## **APPENDIX B.1 SERIOUS LIVER INJURY/DISEASE OUTCOME EVENT DEFINITION; BASELINE EXCLUSIONARY SCREENING**

### **ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions**

#### **History of Serious Liver Injury/Disease**

##### **ICD-9-CM Diagnoses**

277.4 Disorders of bilirubin excretion  
570 Acute and subacute necrosis of liver  
571.5 Cirrhosis of liver without mention of alcohol  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
572.8 Other sequelae of chronic liver disease\*  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test  
V42.7 Liver replaced by transplant

##### **ICD-9-CM Procedures**

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver  
50.91 Percutaneous aspiration of liver

##### **CPT® Procedures**

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

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#### **History of Viral Hepatitis**

##### **ICD-9-CM Diagnoses**

070.0 Viral Hepatitis A With Hepatic Coma  
070.1 Viral Hepatitis A Without Hepatic Coma  
070.2 Viral Hepatitis B With Hepatic Coma  
070.20 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified Without Hepatitis Delta

070.21 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified With Hepatitis Delta  
070.22 Chronic Viral Hepatitis B With Hepatic Coma Without Hepatitis Delta  
070.23 Chronic Viral Hepatitis B With Hepatic Coma With Hepatitis Delta  
070.3 Viral Hepatitis B Without Mention Of Hepatic Coma  
070.30 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified Without Hepatitis Delta  
070.31 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified With Hepatitis Delta  
070.32 Chronic Viral Hepatitis B Without Hepatic Coma Without Hepatitis Delta  
070.33 Chronic Viral Hepatitis B Without Hepatic Coma With Hepatitis Delta  
070.4 Other Specified Viral Hepatitis With Hepatic Coma  
070.41 Acute Hepatitis C With Hepatic Coma  
070.42 Hepatitis Delta Without Active Hepatitis B Disease With Hepatic Coma  
070.43 Hepatitis E With Hepatic Coma  
070.44 Chronic Hepatitis C With Hepatic Coma  
070.49 Other Specified Viral Hepatitis With Hepatic Coma  
070.5 Other Specified Viral Hepatitis Without Mention Of Hepatic Coma  
070.51 Acute Hepatitis C Without Mention Of Hepatic Coma  
070.52 Hepatitis Delta Without Active Hepatitis B Disease Or Hepatic Coma  
070.53 Hepatitis E Without Hepatic Coma  
070.54 Chronic Hepatitis C Without Hepatic Coma  
070.59 Other Specified Viral Hepatitis Without Hepatic Coma  
070.7 Unspecified Viral Hepatitis C  
070.70 Unspecified Viral Hepatitis C Without Hepatic Coma  
070.71 Unspecified Viral Hepatitis C With Hepatic Coma  
V02.61 Carrier Or Suspected Carrier Of Hepatitis B  
V02.62 Carrier Or Suspected Carrier Of Hepatitis C

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### **Non-Specific – Other Related Hepatitis**

#### **ICD-9-CM Diagnoses**

070.6 Unspecified Viral Hepatitis With Hepatic Coma  
070.9 Unspecified Viral Hepatitis Without Hepatic Coma  
072.71 Mumps Hepatitis  
091.62 Secondary Syphilitic Hepatitis  
571.4 Chronic Hepatitis  
571.40 Chronic Hepatitis, Unspecified  
571.41 Chronic Persistent Hepatitis  
571.42 Autoimmune Hepatitis  
571.49 Other Chronic Hepatitis  
571.8 Other Chronic Nonalcoholic Liver Disease  
572.0 Abscess of Liver  
V02.6 Carrier Or Suspected Carrier Of Viral Hepatitis  
V02.60 Carrier Or Suspected Carrier Of Viral Hepatitis Unspecified  
V02.69 Carrier Or Suspected Carrier Of Other Viral Hepatitis

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### **History of Hereditary Conditions**

#### **ICD-9-CM Diagnoses**

271.0 Glycogenosis

271.1 Galactosemia  
273.4 Alpha-1-Antitrypsin Deficiency  
275.0 Disorders Of Iron Metabolism  
275.01 Hereditary Hemochromatosis  
275.03 Other Hemochromatosis  
275.1 Disorders Of Copper Metabolism  
759.89 Other Specified Congenital Anomalies (Alagille syndrome)

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## **APPENDIX B.2      SERIOUS LIVER INJURY/DISEASE OUTCOME EVENT DEFINITION**

### **ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions**

#### **ICD-9-CM Diagnoses**

277.4 Disorders of bilirubin excretion  
570 Acute and subacute necrosis of liver  
571.5 Cirrhosis of liver without mention of alcohol  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
572.8 Other sequelae of chronic liver disease\*  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test  
V42.7 Liver replaced by transplant

#### **ICD-9-CM Procedures**

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver  
50.91 Percutaneous aspiration of liver

#### **CPT® Procedures**

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

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\* Approved for definition inclusion on October 22, 2013.

Also approved for removal from the definition:

789.1 Hepatomegaly, and  
791.4 Biliuria

## **APPENDIX B.3      SLD OUTCOME EVENT DEFINITION - GROUP A CODES**

### **Group A Codes (usually reflects Liver Injury/Disease)**

#### **ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions**

**ICD-9-CM Diagnosis** (may occur in any code position; inpatient setting):

570    Acute and subacute necrosis of liver  
572.2    Hepatic coma  
572.4    Hepatorenal syndrome  
V42.7    Liver replaced by transplant

**ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

50.5    Liver transplant  
50.51    Auxiliary liver transplant  
50.59    Other transplant of liver

**CPT®** (may occur in any code position; inpatient setting):

47135    Liver allotransplantation; orthotopic, partial or whole  
47136    Liver allotransplantation; heterotopic, partial or whole

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## APPENDIX B.4 SLD OUTCOME EVENT DEFINITION - GROUP B CODES

### Group B Codes (highly suspicious, suggestive of Liver Injury/Disease)

#### ICD-9-CM Diagnosis and Procedure Codes / CPT Code Descriptions

**ICD-9-CM Diagnosis** (diagnosis must be an inpatient primary discharge diagnosis):

- 277.4 Disorders of bilirubin excretion
- 571.5 Cirrhosis of liver without mention of alcohol
- 572.8 Other sequelae of chronic liver disease\*
- 573.0 Chronic passive congestion of liver
- 573.3 Hepatitis, unspecified
- 573.8 Other specified disorders of liver
- 573.9 Unspecified disorder of liver
- 782.4 Jaundice, unspecified
- 794.8 Nonspecific abnormal results of liver function test

**ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

- 50.11 Closed (percutaneous) [needle] biopsy of liver
- 50.12 Open biopsy of liver
- 50.13 Transjugular liver biopsy
- 50.14 Laparoscopic liver biopsy
- 50.91 Percutaneous aspiration of liver

**CPT**<sup>®</sup> (may occur in any code position; inpatient setting):

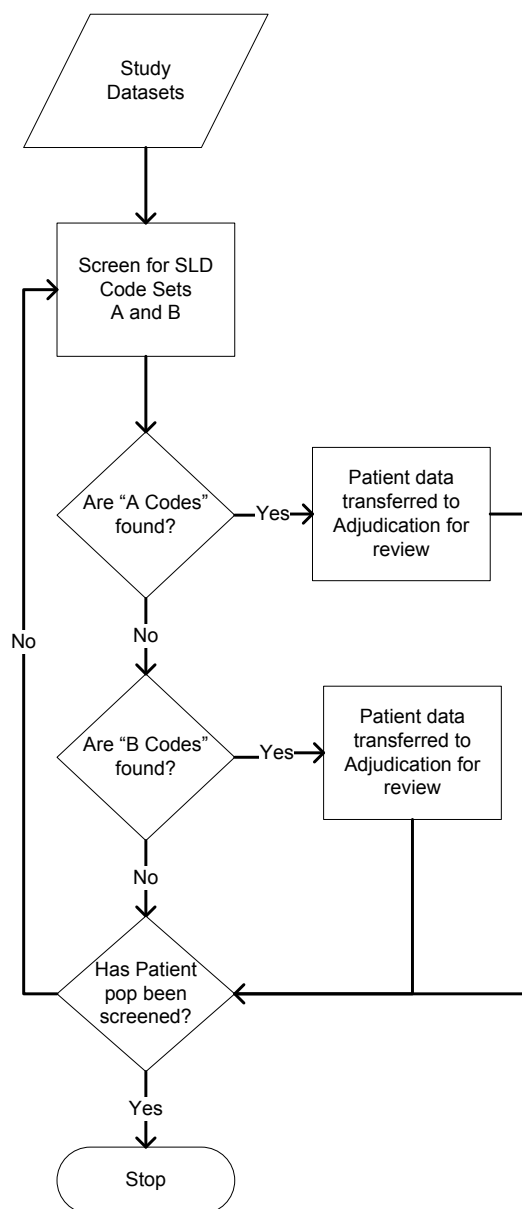
- 47000 Biopsy of liver, needle; percutaneous
- 47001 Biopsy of liver, needle; done at time of other major procedure
- 47100 Biopsy of liver, wedge
- 78205 Liver imaging (SPECT)
- 78206 Liver imaging (SPECT); with vascular flow

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\* Approved for definition inclusion on October 22, 2013.



## APPENDIX B.5 ALGORITHM FOR SELECTION OF SLD OUTCOME EVENTS FOR ADJUDICATION



### A CODES

**ICD-9-CM Diagnosis (may occur in any code position; inpatient setting)**

570 Acute and subacute necrosis of liver  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
V42.7 Liver replaced by transplant

**ICD-9-CM Procedures (may occur in any code position; inpatient setting)**

50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver

**CPT (may occur in any code position; inpatient setting)**

47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole

### B CODES

**ICD-9-CM Diagnosis (must be a primary discharge diagnosis)**

277.4 Disorders of bilirubin excretion  
571.5 Cirrhosis of liver without mention of alcohol  
572.8 Other sequelae of chronic liver disease  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test

**ICD-9-CM Procedures (may occur in any code position; inpatient setting)**

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.91 Percutaneous aspiration of liver

**CPT (may occur in any code position; inpatient setting)**

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

## **APPENDIX C.1.1 INTERSTITIAL LUNG DISEASE OUTCOME EVENT - NARROW DEFINITION; BASELINE EXCLUSIONARY SCREENING**

### **ICD-9-CM Code Descriptions**

#### **History of Interstitial Lung Disease**

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

---

#### **History of Pneumonia**

|        |                                                                |
|--------|----------------------------------------------------------------|
| 480    | Viral Pneumonia                                                |
| 480.0  | Pneumonia Due To Adenovirus                                    |
| 480.1  | Pneumonia Due To Respiratory Syncytial Virus                   |
| 480.2  | Pneumonia Due To Parainfluenza Virus                           |
| 480.3  | Pneumonia Due To Sars-Associated Coronavirus                   |
| 480.8  | Pneumonia Due To Other Virus Not Elsewhere Classified          |
| 480.9  | Viral Pneumonia Unspecified                                    |
| 481    | Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia]    |
| 482    | Other Bacterial Pneumonia                                      |
| 482.0  | Pneumonia Due To Klebsiella Pneumoniae                         |
| 482.1  | Pneumonia Due To Pseudomonas                                   |
| 482.2  | Pneumonia Due To Hemophilus Influenzae (H. Influenzae)         |
| 482.3  | Pneumonia Due To Streptococcus                                 |
| 482.30 | Pneumonia Due To Streptococcus Unspecified                     |
| 482.31 | Pneumonia Due To Streptococcus Group A                         |
| 482.32 | Pneumonia Due To Streptococcus Group B                         |
| 482.39 | Pneumonia Due To Other Streptococcus                           |
| 482.4  | Pneumonia Due To Staphylococcus                                |
| 482.40 | Pneumonia Due To Staphylococcus Unspecified                    |
| 482.41 | Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus |
| 482.42 | Methicillin Resistant Pneumonia Due To Staphylococcus Aureus   |
| 482.49 | Other Staphylococcus Pneumonia                                 |
| 482.8  | Pneumonia Due To Other Specified Bacteria                      |
| 482.81 | Pneumonia Due To Anaerobes                                     |
| 482.82 | Pneumonia Due To Escherichia Coli [E.Coli]                     |
| 482.83 | Pneumonia Due To Other Gram-Negative Bacteria                  |
| 482.84 | Pneumonia Due To Legionnaires' Disease                         |
| 482.89 | Pneumonia Due To Other Specified Bacteria                      |
| 482.9  | Bacterial Pneumonia Unspecified                                |

483.8 Pneumonia Due To Other Specified Organism  
485 Bronchopneumonia Organism Unspecified  
486 Pneumonia Organism Unspecified  
487.0 Influenza With Pneumonia  
507.0 Pneumonitis due to inhalation of food or vomitus  
V12.61 Personal History Of Pneumonia (Recurrent)

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## History of Sarcoidosis

135 Sarcoidosis

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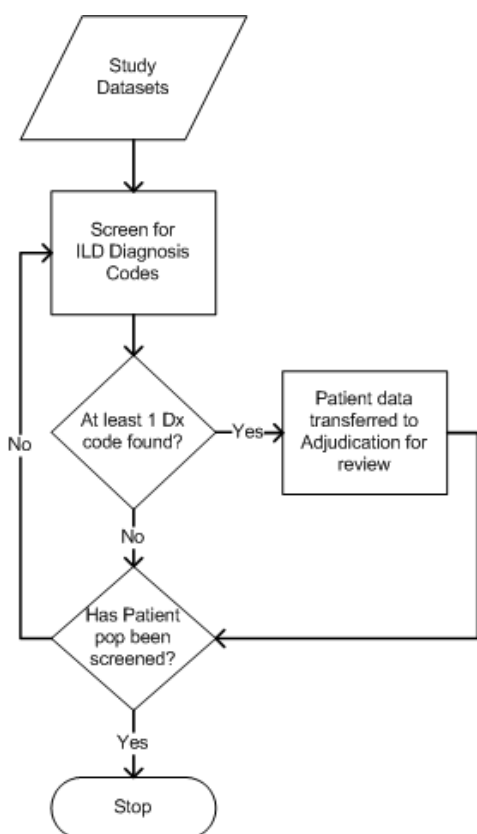
## APPENDIX C.1.2    ILD OUTCOME EVENT - NARROW DEFINITION

### **ICD-9-CM Code Descriptions** (Codes must be an inpatient discharge diagnosis)

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

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### APPENDIX C.1.3 ALGORITHM FOR SELECTION OF SUSPECTED ILD (NARROW) OUTCOME EVENTS FOR ADJUDICATION



Code occurrence must be among the hospital discharge diagnoses.

#### ICD-9-CM

| Code   | Description                                                      |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

## **APPENDIX C.2.1 INTERSTITIAL LUNG DISEASE OUTCOME EVENT – BROAD DEFINITION; BASELINE EXCLUSIONARY SCREENING**

### **ICD-9-CM Code Descriptions**

#### **History of Interstitial Lung Disease (Broad)**

|        |                                                                                     |
|--------|-------------------------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                                     |
| 515    | Post-inflammatory pulmonary fibrosis                                                |
| 516.3  | Idiopathic fibrosing alveolitis                                                     |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP)                    |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                                                 |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)                             |
| 516.33 | Acute interstitial pneumonitis (AIP)                                                |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)                        |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                                    |
| 516.36 | Cryptogenic organizing pneumonia (COP)                                              |
| 516.37 | Desquamative interstitial pneumonia (DIP)                                           |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies                        |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy                              |
| 518    | Other diseases of lung                                                              |
| 518.0  | Pulmonary collapse                                                                  |
| 518.1  | Interstitial emphysema                                                              |
| 518.2  | Compensatory emphysema                                                              |
| 518.3  | Pulmonary eosinophilia                                                              |
| 518.4  | Acute edema of lung unspecified                                                     |
| 518.5  | Pulmonary insufficiency following trauma and surgery                                |
| 518.51 | Acute respiratory failure following trauma and surgery                              |
| 518.52 | Other pulmonary insufficiency not elsewhere classified following trauma and surgery |
| 518.53 | Acute and chronic respiratory failure following trauma and surgery                  |
| 518.6  | Allergic bronchopulmonary aspergilliosis                                            |
| 518.7  | Transfusion related acute lung injury (trali)                                       |
| 518.8  | Other diseases of lung                                                              |
| 518.81 | Acute respiratory failure                                                           |
| 518.82 | Other pulmonary insufficiency not elsewhere classified                              |
| 518.83 | Chronic respiratory failure                                                         |
| 518.84 | Acute and chronic respiratory failure                                               |
| 518.89 | Other diseases of lung not elsewhere classified                                     |

---

#### **History of Pneumonia**

|       |                                                             |
|-------|-------------------------------------------------------------|
| 480   | Viral Pneumonia                                             |
| 480.0 | Pneumonia Due To Adenovirus                                 |
| 480.1 | Pneumonia Due To Respiratory Syncytial Virus                |
| 480.2 | Pneumonia Due To Parainfluenza Virus                        |
| 480.3 | Pneumonia Due To Sars-Associated Coronavirus                |
| 480.8 | Pneumonia Due To Other Virus Not Elsewhere Classified       |
| 480.9 | Viral Pneumonia Unspecified                                 |
| 481   | Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia] |
| 482   | Other Bacterial Pneumonia                                   |
| 482.0 | Pneumonia Due To Klebsiella Pneumoniae                      |
| 482.1 | Pneumonia Due To Pseudomonas                                |

482.2 Pneumonia Due To Hemophilus Influenzae (H. Influenzae)  
482.3 Pneumonia Due To Streptococcus  
482.30 Pneumonia Due To Streptococcus Unspecified  
482.31 Pneumonia Due To Streptococcus Group A  
482.32 Pneumonia Due To Streptococcus Group B  
482.39 Pneumonia Due To Other Streptococcus  
482.4 Pneumonia Due To Staphylococcus  
482.40 Pneumonia Due To Staphylococcus Unspecified  
482.41 Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus  
482.42 Methicillin Resistant Pneumonia Due To Staphylococcus Aureus  
482.49 Other Staphylococcus Pneumonia  
482.8 Pneumonia Due To Other Specified Bacteria  
482.81 Pneumonia Due To Anaerobes  
482.82 Pneumonia Due To Escherichia Coli [E.Coli]  
482.83 Pneumonia Due To Other Gram-Negative Bacteria  
482.84 Pneumonia Due To Legionnaires' Disease  
482.89 Pneumonia Due To Other Specified Bacteria  
482.9 Bacterial Pneumonia Unspecified  
483.8 Pneumonia Due To Other Specified Organism  
485 Bronchopneumonia Organism Unspecified  
486 Pneumonia Organism Unspecified  
487.0 Influenza With Pneumonia  
507.0 Pneumonitis due to inhalation of food or vomitus  
V12.61 Personal History Of Pneumonia (Recurrent)

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## History of Sarcoidosis

135 Sarcoidosis

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## APPENDIX C.2.2 ILD OUTCOME EVENT – BROAD DEFINITION

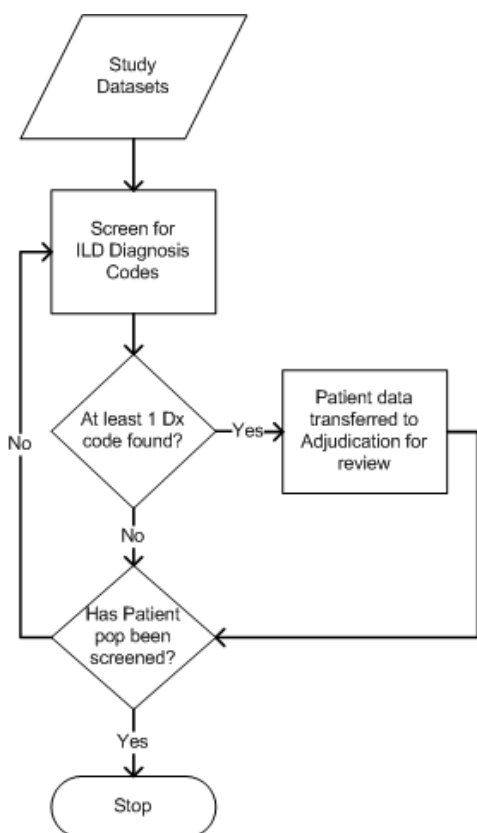
### ICD-9-CM Code Description

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                  |
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |
| 518.82 | Other pulmonary insufficiency, not elsewhere classified          |

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## APPENDIX C.2.3 ALGORITHM FOR SELECTION OF SUSPECTED ILD (BROAD) OUTCOME EVENTS FOR ADJUDICATION



Code occurrence must be among the hospital discharge diagnoses.

### ICD-9-CM

| Code   | Description                                                      |
|--------|------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                  |
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |
| 518.82 | Acute Respiratory Distress Syndrome                              |

## APPENDIX D. LIVER INJURY/DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Codes to identify patients with pre-existing liver/biliary diseases, and chronic liver disease.

| ICD-9-CM                                   | Diagnosis Code Description                                                                     |
|--------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>History of Alcoholism</b>               |                                                                                                |
| 571.0                                      | Alcoholic Fatty Liver                                                                          |
| 571.1                                      | Acute Alcoholic Hepatitis                                                                      |
| 571.2                                      | Alcoholic Cirrhosis Of Liver                                                                   |
| 571.3                                      | Unspecified Alcoholic Liver Damage                                                             |
| <b>History of Biliary Duct Disorders</b>   |                                                                                                |
| 574.00                                     | Calculus Of Gallbladder With Acute Cholecystitis Without Obstruction                           |
| 574.01                                     | Calculus Of Gallbladder With Acute Cholecystitis With Obstruction                              |
| 574.10                                     | Calculus Of Gallbladder With Other Cholecystitis Without Obstruction                           |
| 574.11                                     | Calculus Of Gallbladder With Other Cholecystitis With Obstruction                              |
| 574.20                                     | Calculus Of Gallbladder Without Cholecystitis Without Obstruction                              |
| 574.21                                     | Calculus Of Gallbladder Without Cholecystitis With Obstruction                                 |
| 574.30                                     | Calculus Of Bile Duct With Acute Cholecystitis Without Obstruction                             |
| 574.31                                     | Calculus Of Bile Duct With Acute Cholecystitis With Obstruction                                |
| 574.40                                     | Calculus Of Bile Duct With Other Cholecystitis                                                 |
| 574.41                                     | Calculus Of Bile Duct With Other Cholecystitis Without Obstruction                             |
| 574.50                                     | Calculus Of Bile Duct With Other Cholecystitis With Obstruction                                |
| 574.51                                     | Calculus Of Bile Duct Without Mention Of Cholecystitis                                         |
| 574.60                                     | Calculus Of Bile Duct Without Cholecystitis Without Obstruction                                |
| 574.61                                     | Calculus Of Bile Duct Without Cholecystitis With Obstruction                                   |
| 574.70                                     | Calculus Of Gallbladder And Bile Duct With Acute Cholecystitis                                 |
| 574.71                                     | Calculus Of Gallbladder And Bile Duct With Other Cholecystitis, With Obstruction               |
| 574.80                                     | Calculus Of Gallbladder And Bile Duct With Acute And Chronic Cholecystitis Without Obstruction |
| 574.81                                     | Calculus Of Gallbladder And Bile Duct With Acute And Chronic Cholecystitis With Obstruction    |
| 574.90                                     | Calculus Of Gallbladder And Bile Duct Without Cholecystitis Without Obstruction                |
| 574.91                                     | Calculus Of Gallbladder And Bile Duct Without Cholecystitis With Obstruction                   |
| 575.0                                      | Acute Cholecystitis                                                                            |
| 575.1                                      | Other Cholecystitis                                                                            |
| 575.10                                     | Cholecystitis Unspecified                                                                      |
| 575.11                                     | Chronic Cholecystitis                                                                          |
| 575.12                                     | Acute And Chronic Cholecystitis                                                                |
| 575.2                                      | Obstruction Of Gallbladder                                                                     |
| 575.3                                      | Hydrops Of Gallbladder                                                                         |
| 575.4                                      | Perforation Of Gallbladder                                                                     |
| 575.5                                      | Fistula Of Gallbladder                                                                         |
| 575.6                                      | Cholesterolosis Of Gallbladder                                                                 |
| 575.8                                      | Other Specified Disorders Of Gallbladder                                                       |
| 575.9                                      | Unspecified Disorder Of Gallbladder                                                            |
| 576.1                                      | Cholangitis                                                                                    |
| <b>History of Congestive Heart Failure</b> |                                                                                                |
| 428                                        | Heart Failure                                                                                  |
| 428.0                                      | Congestive Heart Failure Unspecified                                                           |
| 428.1                                      | Left Heart Failure                                                                             |
| 428.2                                      | Systolic Heart Failure                                                                         |
| 428.20                                     | Unspecified Systolic Heart Failure                                                             |
| 428.21                                     | Acute Systolic Heart Failure                                                                   |
| 428.22                                     | Chronic Systolic Heart Failure                                                                 |
| 428.23                                     | Acute On Chronic Systolic Heart Failure                                                        |
| 428.3                                      | Diastolic Heart Failure                                                                        |
| 428.30                                     | Unspecified Diastolic Heart Failure                                                            |
| 428.31                                     | Acute Diastolic Heart Failure                                                                  |

|        |                                                                |
|--------|----------------------------------------------------------------|
| 428.32 | Chronic Diastolic Heart Failure                                |
| 428.33 | Acute On Chronic Diastolic Heart Failure                       |
| 428.4  | Combined Systolic And Diastolic Heart Failure                  |
| 428.40 | Unspecified Combined Systolic And Diastolic Heart Failure      |
| 428.41 | Acute Combined Systolic And Diastolic Heart Failure            |
| 428.42 | Chronic Combined Systolic And Diastolic Heart Failure          |
| 428.43 | Acute On Chronic Combined Systolic And Diastolic Heart Failure |
| 428.9  | Heart Failure Unspecified                                      |

#### History of Diabetes

|        |                                                               |
|--------|---------------------------------------------------------------|
| 250.xx | Diabetes Mellitus                                             |
| V18.0  | Family History Of Diabetes Mellitus                           |
| V18.1  | Family History Of Other Endocrine And Metabolic Diseases      |
| V18.11 | Family History Of Multiple Endocrine Neoplasia [Men] Syndrome |
| V18.19 | Family History Of Other Endocrine And Metabolic Diseases      |

**Medication Proxy** (Occurrence of medication prior to index date) [from Facts & Comparisons eAnswers – Antidiabetic Agents, accessed April 6, 2015.]

acarbose  
albiglutide  
alogliptin  
bromocriptine  
canagliflozin  
chlorpropamide  
dapagliflozin  
dulaglutide  
empagliflozin  
exenatide  
glimepiride  
glipizide  
glyburide ( glibenclamide)  
insulin aspart  
insulin detemir  
insulin glargine (rdna origin)  
insulin glulisine  
insulin isophane ( nph)  
insulin isophane (nph) /insulin regular  
insulin lispro  
insulin regular  
linagliptin  
liraglutide  
metformin hydrochloride  
miglitol  
nateglinide  
pioglitazone  
pramlintide  
repaglinide  
rosiglitazone  
saxagliptin  
sitagliptin  
tolazamide  
tolbutamide  
alogliptin/metformin hydrochloride  
alogliptin/pioglitazone  
canagliflozin/metformin hydrochloride  
dapagliflozin/metformin  
empagliflozin/linagliptin  
glipizide/metformin hydrochloride  
glyburide/metformin hydrochloride  
linagliptin/metformin hydrochloride  
pioglitazone/glimepiride  
pioglitazone/metformin hydrochloride  
repaglinide/metformin hydrochloride

rosiglitazone/glimepiride  
rosiglitazone/metformin hydrochloride  
saxagliptin/metformin hydrochloride  
sitagliptin/metformin hydrochloride  
sitagliptin/simvastatin

#### History of Obesity

|        |                                                 |
|--------|-------------------------------------------------|
| 278    | Overweight, Obesity And Other Hyperalimentation |
| 278.0  | Overweight And Obesity                          |
| 278.00 | Obesity Unspecified                             |
| 278.01 | Morbid Obesity                                  |
| 278.02 | Overweight                                      |
| 278.03 | Obesity Hypoventilation Syndrome                |
| V85.41 | BMI 40.0 – 44.9, adult                          |
| V85.42 | BMI 45.0 – 49.9, adult                          |
| V85.43 | BMI 50.0 – 59.9, adult                          |
| V85.44 | BMI 60.0 – 69.9, adult                          |
| V85.45 | BMI 70 and over, adult                          |

#### Other Anti-arrhythmic Agents (Therapeutic class # 240404\*)

|                                            |                             |
|--------------------------------------------|-----------------------------|
| Bretylum Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylum Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride           | Quinidine Polygalacturonate |
| Disopyramide Phosphate                     | Quinidine Sulfate           |
| Lidocaine Hydrochloride                    | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                   |                             |

\* Systemic use; screen for only the agents list above.

**Hepatotoxic Medications\* [Note: current list refers to DoD data; a combined DoD & HIRD list of medications will be provided.]**

| Generic Name (Alias)<br>Study Period: 7/20/2008 to 9/30/2014  | Product Name                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Acetaminophen (N-Acetyl-P-Aminophenol; APAP)</b>           | Acetaminophen<br>Children's Tylenol<br>Children's Q-PAP<br>Genapap<br>Genebs<br>Mapap<br>Mapap Arthritis Pain<br>Pain & Fever<br>Pain Relief<br>Pain Relief Extra Strength<br>Pain Reliever<br>Q-PAP<br>Sedapap<br>Tylenol 8 Hour<br>Tylenol Cold<br>Tylenol Extra Strength<br>Tylenol |
| <b>Acetaminophen in Combination Products</b>                  |                                                                                                                                                                                                                                                                                        |
| <i>Acetaminophen/Aspirin/Caffeine/Codeine</i>                 | <i>Acetaminophen/Aspirin/Caffeine/ Codeine</i>                                                                                                                                                                                                                                         |
| Acetaminophen/Aspirin/Caffeine/Salicylamide                   | Levacet                                                                                                                                                                                                                                                                                |
| Acetaminophen/Atropine/Caffeine/Ephedrine                     | Acetaminophen/Atropine/Caffeine/Ephedrine                                                                                                                                                                                                                                              |
| Acetaminophen/Caffeine/Dihydrocodeine Bitartrate              | Acetaminophen/ Caffeine/ Dihydrocodeine Bitartrate                                                                                                                                                                                                                                     |
|                                                               | Trezix                                                                                                                                                                                                                                                                                 |
| Acetaminophen/Butalbital                                      | BUPAP                                                                                                                                                                                                                                                                                  |
|                                                               | Cephadyn                                                                                                                                                                                                                                                                               |
|                                                               | Sedapap                                                                                                                                                                                                                                                                                |
|                                                               | Phrenilin Forte                                                                                                                                                                                                                                                                        |
| Acetaminophen/Butalbital/Caffeine                             | Acetaminophen/Butalbital/Caffeine                                                                                                                                                                                                                                                      |
|                                                               | Dolgic Plus                                                                                                                                                                                                                                                                            |
|                                                               | Esgic                                                                                                                                                                                                                                                                                  |
|                                                               | Esgic-Plus                                                                                                                                                                                                                                                                             |
|                                                               | Fioricet                                                                                                                                                                                                                                                                               |
|                                                               | Zebutal                                                                                                                                                                                                                                                                                |
| Acetaminophen/Butalbital/Codeine Phosphate                    | Acetaminophen/Butalbital/Codeine Phosphate                                                                                                                                                                                                                                             |
| Acetaminophen/Butalbital/Caffeine/Codeine                     | Acetaminophen/ Butalbital /Caffeine/Codeine                                                                                                                                                                                                                                            |
|                                                               | Fioricet with Codeine                                                                                                                                                                                                                                                                  |
| Acetaminophen/Caffeine/ Pyrilamine                            | Midol Maximum Strength Menstrual                                                                                                                                                                                                                                                       |
| Acetaminophen/Calcium Carbonate                               | Various                                                                                                                                                                                                                                                                                |
| Acetaminophen/Codeine Phosphate                               | Acetaminophen/Codeine Phosphate                                                                                                                                                                                                                                                        |
|                                                               | Tylenol with Codeine #3                                                                                                                                                                                                                                                                |
| Acetaminophen/Dextromethorphan/Diphenhydramine/ Phenylephrine | Respa C&C                                                                                                                                                                                                                                                                              |
|                                                               | Respa C&C IR                                                                                                                                                                                                                                                                           |
| Acetaminophen/Dextromethorphan                                | Various                                                                                                                                                                                                                                                                                |
| Acetaminophen/Guaifenesin                                     | Various                                                                                                                                                                                                                                                                                |
| Acetaminophen/ Hydrocodone Bitartrate                         | Acetaminophen/ Hydrocodone Bitartrate                                                                                                                                                                                                                                                  |
|                                                               | Hycet                                                                                                                                                                                                                                                                                  |
|                                                               | Lorcet                                                                                                                                                                                                                                                                                 |
|                                                               | Lortab                                                                                                                                                                                                                                                                                 |

|                                                             |                                                |
|-------------------------------------------------------------|------------------------------------------------|
|                                                             | Norco                                          |
|                                                             | Stagesic                                       |
|                                                             | Vicodin                                        |
|                                                             | Vicodin ES                                     |
|                                                             | Vicodin HP                                     |
|                                                             | Xodol 5-300                                    |
|                                                             | Xodol 10-300                                   |
|                                                             | Zamiset                                        |
|                                                             | Zydene                                         |
| Acetaminophen/Isometheptene Mucate/Caffeine                 | Acetaminophen/Isometheptene Mucate/Caffeine    |
|                                                             | Prodrin                                        |
| Acetaminophen /Isometheptene/Dichloralphenazone             | Acetaminophen/Isometheptene/Dichloralphenazone |
|                                                             | Diacetazone                                    |
|                                                             | Epidrin                                        |
|                                                             | I.D.A.                                         |
|                                                             | Midrin                                         |
|                                                             | Migquin                                        |
|                                                             | Migratine                                      |
|                                                             | Migrazone                                      |
| Acetaminophen/Oxycodone HCL                                 | Acetaminophen/Oxycodone HCL                    |
|                                                             | Endocet                                        |
|                                                             | Magnacet                                       |
|                                                             | Percocet                                       |
|                                                             | Roxicet                                        |
|                                                             | Tylox                                          |
|                                                             | Xolox                                          |
| Acetaminophen/Pentazocine                                   | Acetaminophen/Pentazocine                      |
|                                                             | Talacen                                        |
| Acetaminophen/Pheniramine/Phenylephrine                     | Various                                        |
| Acetaminophen/Doxylamine/Phenylephrine/<br>Dextromethorphan | Various                                        |
| Acetaminophen/Phenylephrine                                 | Various                                        |
| Acetaminophen/Phenyltoloxamine                              | Dologesic                                      |
|                                                             | Flextra-650                                    |
|                                                             | Relagesic                                      |
|                                                             | POLY-650                                       |
|                                                             | RhinoFlex-650                                  |
| Acetaminophen/Phenyltoloxamine/Salicylamide                 | Ed-Flex                                        |
|                                                             | Dolorex                                        |
| Acetaminophen/Propoxyphene HCL                              | Propoxyphene HCL /Acetaminophen                |
| Acetaminophen/Propoxyphene Napsylate                        | Propoxyphene Napsylate/Acetaminophen           |
|                                                             | Balacet 325                                    |
|                                                             | Darvocet A500                                  |
|                                                             | Darvocet-N 100                                 |
|                                                             | Darvocet-N 50                                  |
|                                                             | Propacet                                       |
| Acetaminophen/ Tramadol HCL                                 | Tramadol HCL/Acetaminophen                     |
|                                                             | Ultracet                                       |
| <b>Acitretin</b>                                            | Acitretin                                      |
|                                                             | Soriatane                                      |
| <b>Allopurinol</b>                                          | Allopurinol                                    |
|                                                             | Aloprim                                        |
|                                                             | Lopurin                                        |
|                                                             | Zyloprim                                       |
| <b>Amitriptyline</b>                                        | Amitriptyline                                  |

|                                          |                                    |
|------------------------------------------|------------------------------------|
| Amitriptyline HCL/Chlordiazepoxide       | Amitid                             |
|                                          | Amitril                            |
|                                          | Elavil                             |
|                                          | Endep                              |
|                                          | Amitriptyline HCL/Chlordiazepoxide |
| Amitriptyline HCL/Perphenazine           | Limbitrol                          |
|                                          | Limbitrol DS                       |
|                                          | Amitriptyline HCL/Perphenazine     |
|                                          | Etrafon                            |
|                                          | Etrafon A                          |
| <b>Amoxicillin/Potassium Clavulanate</b> | Etrafon Forte                      |
|                                          | Triavil                            |
|                                          | Amoxicillin-Pot Clavulanate        |
|                                          | Augmentin                          |
|                                          | Augmentin ES 600                   |
| <b>Asparaginase Erwinia Chrysanthemi</b> | Augmentin XR                       |
|                                          | Erwinaze                           |
| <b>Azathioprine</b>                      | Azathioprine                       |
|                                          | Azasan                             |
|                                          | Imuran                             |
| <b>Baclofen</b>                          | Baclofen                           |
|                                          | Gablofen                           |
|                                          | Kemstro                            |
|                                          | Lioresal                           |
| <b>Bosentan</b>                          | Tracleer                           |
| <b>Ciprofloxacin</b>                     | Ciprofloxacin                      |
|                                          | Cipro                              |
|                                          | Cipro XR                           |
|                                          | Proquin XR                         |
| <b>Clindamycin</b>                       | Clindamycin Phosphate              |
|                                          | Clindamycin HCL                    |
|                                          | Clindamycin Palmitate HCl          |
|                                          | Cleocin                            |
| <b>Chlorpromazine HCL</b>                | Chlorpromazine                     |
|                                          | Chlorpromazine Intensol            |
|                                          | Promapar                           |
|                                          | Sonazine                           |
|                                          | Thorazine                          |
| <b>Cyclophosphamide</b>                  | Cyclophosphamide                   |
|                                          | Cytosan                            |
|                                          | Cytosan Lyophilized                |
|                                          | Lyophilized Cytosan                |
|                                          | Neosar                             |
| <b>Cytarabine</b>                        | Cytarabine                         |
|                                          | Cytosar-U                          |
|                                          | Depocyt                            |
| <b>Danazol</b>                           | Danazol                            |
|                                          | Danocrine                          |
| <b>Dantrolene Sodium</b>                 | Dantrium                           |
|                                          | Dantrolene Sodium                  |
|                                          | Revonto                            |
|                                          | Ryanodex                           |
| <b>Dapsone</b>                           | Dapsone                            |
| <b>Deferasirox</b>                       | Deferasirox                        |

|                                            |                               |
|--------------------------------------------|-------------------------------|
|                                            | Exjade                        |
|                                            | Jadenu                        |
| <b>Desflurane</b>                          | Suprane                       |
| <b>Diclofenac</b>                          | Zorvolex                      |
| Diclofenac Sodium                          | Diclofenac Sodium             |
|                                            | DSG Pak                       |
|                                            | Dyloject                      |
|                                            | Pennsaid                      |
|                                            | Rexaphenac                    |
|                                            | Solaraze                      |
|                                            | Voltaren                      |
|                                            | Voltaren-XR                   |
| Diclofenac Potassium                       | Cambia                        |
|                                            | Cataflam                      |
|                                            | Diclofenac Potassium          |
|                                            | Zipsor                        |
| Diclofenac Epolamine                       | Flector                       |
| Diclofenac Sodium/Misoprostol              | Arthrotec                     |
|                                            | Diclofenac Sodium/Misoprostol |
| <b>Disulfiram</b>                          | Antabuse                      |
|                                            | Disulfiram                    |
| <b>Eltrombopag Olamine</b>                 | Promacta                      |
| <b>Enflurane</b>                           | Enflurane                     |
|                                            | Ethrane                       |
|                                            | Compound 347                  |
| <b>Erythromycin Estolate</b>               | Erythromycin Estolate         |
| Erythromycin Estolate/Sulfisoxazole Acetyl | Ilosone                       |
|                                            | Ilosone Sulfa                 |
| <b>Felbamate</b>                           | Felbamate                     |
|                                            | Felbatol                      |
| <b>Fenofibrate</b>                         |                               |
| Choline Fenofibrate                        | Fenofibric acid               |
|                                            | Trilipix                      |
| Fenofibrate                                | Fenofibrate                   |
|                                            | Lipidil                       |
|                                            | Fenoglide                     |
|                                            | Lipofen                       |
|                                            | Lofibra                       |
|                                            | Tricor                        |
|                                            | Triglide                      |
| Fenofibrate micronized                     | Antara (micronized)           |
|                                            | Fenofibrate micronized        |
|                                            | Tricor (micronized)           |
| <b>Fluconazole</b>                         | Fluconazole                   |
|                                            | Diflucan                      |
| <b>Flutamide</b>                           | Flutamide                     |
| <b>Fluvastatin</b>                         | Fluvastatin                   |
| Fluvastatin Sodium                         | Fluvastatin Sodium            |
|                                            | Lescol                        |
|                                            | Lescol XL                     |
| <b>Gemfibrozil</b>                         | Gemfibrozil                   |
|                                            | Lopid                         |
| <b>Halothane</b>                           | Halothane                     |
|                                            | Fluothane                     |
| <b>Hydralazine HCL</b>                     | Hydralazine                   |



|                                                                               |                                                                                                                                     |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Hydralazine/Hydrochlorothiazide                                               | Dralzine<br>Apresoline<br>Apresazide<br>Apresoline-Esidrix<br>Hydra-Zide<br>Hydralazine/Hydrochlorothiazide                         |
| Hydralazine/Isosorbide Dinitrate<br>Hydralazine/Hydrochlorothiazide/Reserpine | BiDil<br>Cam-Ap-Es<br>Hydralazine/Hydrochlorothiazide/Reserpine<br>Hydrap-ES<br>Hydroserpine plus (r-h-h)<br>SER-A-GEN<br>SER-AP-ES |
| Hydralazine/Reserpine                                                         | Unipres<br>Dralserp<br>Serpasil-Apresoline                                                                                          |
| <b>Infliximab</b>                                                             | Remicade                                                                                                                            |
| <b>Interferon beta-1a</b>                                                     | Avonex<br>Rebif<br>Plegridy                                                                                                         |
| Peginterferon Beta-1a                                                         |                                                                                                                                     |
| <b>Irinotecan HCL</b>                                                         | Camptosar<br>Irinotecan<br>Onivyde                                                                                                  |
| <b>Isoflurane</b>                                                             | Isoflurane<br>Forane<br>Terrell                                                                                                     |
| <b>Isoniazid (Isonicotinic acid hydrazide; INH)</b>                           | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid<br>Nydrasid<br>Rimifon<br>Stanozide<br>Rifamate<br>Isoniazid/Rifampin        |
| Isoniazid/Rifampin                                                            |                                                                                                                                     |
| Isoniazid/Pyrazinamide/Rifampin                                               | Rifater                                                                                                                             |
| <b>Isotretinoin</b>                                                           | Absorica<br>Accutane<br>Amnesteem<br>Claravis<br>Myorisan<br>Sortet<br>Zenatane                                                     |
| <b>Ketoconazole</b>                                                           | Ketoconazole                                                                                                                        |
| <b>Labetalol HCL</b>                                                          | Labetalol HCL<br>Normodyne<br>Trandate<br>Normozide<br>Trandate HCT                                                                 |
| Labetalol HCL/Hydrochlorothiazide                                             |                                                                                                                                     |
| <b>Lapatinib</b>                                                              | Lapatinib                                                                                                                           |
| Lapatinib Ditosylate                                                          | Tykerb                                                                                                                              |
| <b>Leflunomide</b>                                                            | Leflunomide<br>Arava                                                                                                                |
| <b>Mercaptopurine (6-Mercaptopurine; 6-MP)</b>                                | Mercaptopurine                                                                                                                      |

|                                                                                                        |                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                        | Purinethol<br>Purixan                                                                                                                                                           |
| <b>Methyltestosterone</b>                                                                              | Android 10<br>Metandren<br>Methyltestosterone<br>Oreton<br>Oreton Methyl<br>Testred<br>Virilon                                                                                  |
| Methyltestosterone/Esterified Estrogens                                                                | Covaryx<br>Covaryx HS<br>EEMT<br>EEMT HS<br>Esterified Estrogens/Methyltestosterone<br>Esterified Estrogens/Methyltestosterone DS<br>Esterified Estrogens/Methyltestosterone HS |
| Conjugated Estrogens/Methyltestosterone<br>Conjugated Estrogen /Methyltestosterone<br>/Methamphetamine | Premarin with Methyltestosterone<br>Conjugated Estrogen /Methyltestosterone<br>/Methamphetamine                                                                                 |
| <b>Methotrexate (Amethopterin; MTX)</b>                                                                | Methotrexate<br>Abitrexate<br>Folex PFS<br>Mexate-AQ Preserved<br>Mexate<br>Rheumatrex Dose Pack<br>Otrexup<br>Rasuvo<br>Trexall                                                |
| <b>Methyldopa</b>                                                                                      | Methyldopa<br>Aldomet<br>Methyldopate<br>Aldoclor<br>Methyldopa/Chlorothiazide<br>Aldoril<br>Methyldopa/Hydrochlorothiazide                                                     |
| <b>Minocycline</b>                                                                                     | Minocycline<br>Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                                                                                                               |
| <b>Natalizumab</b>                                                                                     | Tysabri                                                                                                                                                                         |
| <b>Nitrofurantoin</b>                                                                                  | Furadantin<br>Furalan<br>Nitrofurantoin<br>Ivadantin<br>Nitrofurantoin Macrocrystal<br>Macroclantin<br>Nitrofurantoin Monohydrate/Macrocrystals<br>Macrobid                     |
| <b>Oxandrolone</b>                                                                                     | Oxandrolone<br>Oxandrin                                                                                                                                                         |
| <b>Oxymetholone</b>                                                                                    | Anadrol-50                                                                                                                                                                      |
| <b>Pazopanib HCL</b>                                                                                   | Votrient                                                                                                                                                                        |
| <b>Phenytoin</b>                                                                                       | Phenytoin                                                                                                                                                                       |

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Phenytoin Sodium                               | Dilantin<br>Phenytoin Sodium<br>Dilantin<br>Phenytek<br>Phenytek<br>Diphenylan Sodium<br>Fosphenytoin Sodium<br>Cerebyx<br>Mesantoin                                                                                                                                                                                                                                                                                   |
| Phenytoin Sodium Prompt<br>Fosphenytoin Sodium |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Mephenytoin Sodium                             |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Propylthiouracil (PTU)</b>                  | Propylthiouracil                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Sulindac</b>                                | Sulindac<br>Clinoril                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Telithromycin</b>                           | Ketek                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Testosterone</b>                            | Androderm<br>Androgel<br>Axiron<br>Fortesta<br>Natesto<br>Striant<br>Testoderm<br>Testim<br>Testoderm TTS<br>Testopel<br>Testosterone<br>Depo-Testosterone<br>Testosterone Cypionate<br>Testosterone Enanthate<br>Delatestryl<br>Testosterone Enanthate<br>Testosterone Propionate<br>Aveed<br>Depo-Testadiol<br>Testosterone Cypionate/Estradiol Cypionate<br>Ditrate-ds<br>Testosterone Enanthate/Estradiol Valerate |
| Testosterone Cypionate                         |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Testosterone Enanthate                         |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Testosterone undecanoate                       |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Testosterone Cypionate/Estradiol Cypionate     |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Testosterone Enanthate/Estradiol Valerate      |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Thioridazine HCL</b>                        | Mellaril<br>Thioridazine<br>Thioridazine Intensol                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Tolcapone</b>                               | Tasmar<br>Tolcapone                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Valproate</b>                               |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Divalproex Sodium                              | Divalproex Sodium<br>Depakote<br>Depakote ER<br>Depakote Sprinkles<br>Valproic Acid<br>Depakene<br>Stavzor<br>Valproate Sodium<br>Depacon<br>Depakene                                                                                                                                                                                                                                                                  |
| Valproic Acid                                  |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Valproate Sodium                               |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Zafirlukast</b>                             | Accolate<br>Zafirlukast                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Zileuton</b>                                | Zyflo<br>Zyflo CR                                                                                                                                                                                                                                                                                                                                                                                                      |

\* Systemic use only.

#### References

Pandit A, Sachdeva T, Bafna P. Drug-Induced Hepatotoxicity: A Review. *J Applied Pharma Science* 02 (05); 2012:233-243.

MehtaN, OzickLA, GbadehanE. Drug-Induced Hepatotoxicity. Medscape 2014.  
<http://emedicine.medscape.com/article/169814-overview#a1> Accessed September 20, 2015.

## APPENDIX E. INTERSTITIAL LUNG DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Risk factors and confounders for ILD are defined by the following ICD-9-CM diagnosis/procedure codes, CPT, HCPCS codes, and/or medication name or NDCs.

### ICD-9-CM Code Descriptions

#### Asthma

|        |                                                      |
|--------|------------------------------------------------------|
| 493    | Asthma                                               |
| 493.0  | Extrinsic Asthma                                     |
| 493.00 | Extrinsic Asthma Unspecified                         |
| 493.01 | Extrinsic Asthma With Status Asthmaticus             |
| 493.02 | Extrinsic Asthma With (Acute) Exacerbation           |
| 493.1  | Intrinsic Asthma                                     |
| 493.10 | Intrinsic Asthma Unspecified                         |
| 493.11 | Intrinsic Asthma With Status Asthmaticus             |
| 493.12 | Intrinsic Asthma With (Acute) Exacerbation           |
| 493.2  | Chronic Obstructive Asthma                           |
| 493.20 | Chronic Obstructive Asthma Unspecified               |
| 493.21 | Chronic Obstructive Asthma With Status Asthmaticus   |
| 493.22 | Chronic Obstructive Asthma With (Acute) Exacerbation |
| 493.8  | Other Specified Asthma                               |
| 493.81 | Exercise-Induced Bronchospasm                        |
| 493.82 | Cough Variant Asthma                                 |
| 493.9  | Asthma Unspecified                                   |
| 493.90 | Asthma Unspecified                                   |
| 493.91 | Asthma Unspecified Type With Status Asthmaticus      |
| 493.92 | Asthma Unspecified With (Acute) Exacerbation         |

#### Bronchitis

|        |                                                          |
|--------|----------------------------------------------------------|
| 490    | Bronchitis Not Specified As Acute Or Chronic             |
| 491    | Chronic Bronchitis                                       |
| 491.0  | Simple Chronic Bronchitis                                |
| 491.1  | Mucopurulent Chronic Bronchitis                          |
| 491.2  | Obstructive Chronic Bronchitis                           |
| 491.20 | Obstructive Chronic Bronchitis Without Exacerbation      |
| 491.21 | Obstructive Chronic Bronchitis With (Acute) Exacerbation |
| 491.22 | Obstructive Chronic Bronchitis With Acute Bronchitis     |
| 491.8  | Other Chronic Bronchitis                                 |
| 491.9  | Unspecified Chronic Bronchitis                           |
| 494    | Bronchiectasis                                           |
| 494.0  | Bronchiectasis Without Acute Exacerbation                |
| 494.1  | Bronchiectasis With Acute Exacerbation                   |

#### COPD

|     |                                                     |
|-----|-----------------------------------------------------|
| 496 | Chronic Airway Obstruction Not Elsewhere Classified |
|-----|-----------------------------------------------------|

### Connective Tissue Disease

|        |                                            |
|--------|--------------------------------------------|
| 136.1  | Behçet syndrome (very rare)                |
| 446.21 | Goodpasture syndrome                       |
| 710.0  | Systemic lupus erythematosus               |
| 710.1  | Systemic sclerosis                         |
| 710.2  | Sjögren syndrome                           |
| 710.3  | Dermatomyositis                            |
| 710.4  | Polymyositis                               |
| 710.8  | Mixed connective tissue disease            |
| 710.9  | Undifferentiated connective tissue disease |
| 714.xx | Rheumatoid arthritis                       |
| 720.0  | Ankylosing spondylitis (rare)              |

### Exposure to Occupational and Environmental Pulmonary Diseases

|       |                                                                     |
|-------|---------------------------------------------------------------------|
| 495   | Extrinsic Allergic Alveolitis                                       |
| 495.0 | Farmers' Lung                                                       |
| 495.1 | Bagassosis                                                          |
| 495.2 | Bird-Fanciers' Lung                                                 |
| 495.3 | Suberosis                                                           |
| 495.4 | Malt Workers' Lung                                                  |
| 495.5 | Mushroom Workers' Lung                                              |
| 495.6 | Maple Bark-Strippers' Lung                                          |
| 495.7 | Ventilation Pneumonitis                                             |
| 495.8 | Other Specified Allergic Alveolitis And Pneumonitis                 |
| 495.9 | Unspecified Allergic Alveolitis And Pneumonitis                     |
| 500   | Coal Workers' Pneumoconiosis                                        |
| 501   | Asbestosis                                                          |
| 502   | Pneumoconiosis Due To Other Silica Or Silicates                     |
| 503   | Pneumoconiosis Due To Other Inorganic Dust                          |
| 504   | Pneumonopathy Due To Inhalation Of Other Dust                       |
| 505   | Pneumoconiosis Unspecified                                          |
| 506   | Respiratory Conditions Due To Chemical Fumes And Vapors             |
| 506.0 | Bronchitis And Pneumonitis Due To Fumes And Vapors                  |
| 506.1 | Acute Pulmonary Edema Due To Fumes And Vapors                       |
| 506.2 | Upper Respiratory Inflammation Due To Fumes And Vapors              |
| 506.3 | Other Acute And Subacute Resp Conditions Due To Fumes And Vapors    |
| 506.4 | Chronic Respiratory Conditions Due To Fumes And Vapors              |
| 506.9 | Unspecified Respiratory Conditions Due To Fumes And Vapors          |
| 507   | Pneumonitis Due To Solids And Liquids                               |
| 507.1 | Pneumonitis Due To Inhalation Of Oils And Essences                  |
| 507.8 | Pneumonitis Due To Other Solids And Liquids                         |
| 508   | Respiratory Conditions Due To Other And Unspecified External Agents |
| 508.0 | Acute Pulmonary Manifestations Due To Radiation                     |
| 508.1 | Chronic And Other Pulmonary Manifestations Due To Radiation         |
| 508.2 | Respiratory Conditions Due To Smoke Inhalation                      |
| 508.8 | Respiratory Conditions Due To Other Specified External Agents       |
| 508.9 | Respiratory Conditions Due To Unspecified External Agent            |

### Gastroesophageal Reflux Disease

|        |                                 |
|--------|---------------------------------|
| 530.81 | Gastroesophageal reflux disease |
|--------|---------------------------------|

**Other Anti-arrhythmic Agents (Therapeutic class # 240404\*)**

|                                             |                             |
|---------------------------------------------|-----------------------------|
| Bretylium Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylium Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride            | Quinidine Polygalacturonate |
| Disopyramide Phosphate                      | Quinidine Sulfate           |
| Lidocaine Hydrochloride                     | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                    |                             |

\* screen for only the agents list above

**Oxygen Therapy – CPT Procedure Codes**

| CPT   | CPT Description                                                                                                                                                                                                                                                                                 |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4030F | Long-term oxygen therapy prescribed (more than 15 hours per day) (COPD)                                                                                                                                                                                                                         |
| 82803 | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub>                                                                                                                                                                                    |
| 82805 | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub> (including calculated O <sub>2</sub> saturation); with O <sub>2</sub> saturation, by direct measurement, except pulse oximetry                                                     |
| 82810 | Gases, blood, O <sub>2</sub> saturation only, by direct measurement, except pulse oximetry                                                                                                                                                                                                      |
| 94010 | Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation                                                                                                                                        |
| 94014 | Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and review and interpretation by a physician/other qualified health care professional |
| 94015 | Patient-initiated spirometric recording per 30-day period of time; recording                                                                                                                                                                                                                    |
| 94016 | Patient-initiated spirometric recording per 30-day period of time; review and interpretation only by a physician or other qualified health care professional                                                                                                                                    |
| 94060 | Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator admin                                                                                                                                                                                                      |
| 94070 | Bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (eg, antigen[s], cold air, methacholine)                                                                                                                                         |
| 94150 | Vital capacity, total (separate procedure)                                                                                                                                                                                                                                                      |
| 94200 | Maximum breathing capacity, maximal voluntary ventilation                                                                                                                                                                                                                                       |
| 94250 | Expired gas collection, quantitative, single procedure (separate procedure)                                                                                                                                                                                                                     |
| 94375 | Respiratory flow volume loop                                                                                                                                                                                                                                                                    |
| 94400 | Breathing response to CO <sub>2</sub> (CO <sub>2</sub> response curve)                                                                                                                                                                                                                          |
| 94450 | Breathing response to hypoxia (hypoxia response curve)                                                                                                                                                                                                                                          |
| 94452 | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional;                                                                                                                                                                |
| 94453 | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional; with supplemental oxygen titration                                                                                                                             |
| 94610 | Intrapulmonary surfactant administration by a physician or other qualified health care professional through endotracheal tube                                                                                                                                                                   |
| 94620 | Pulmonary stress testing; simple                                                                                                                                                                                                                                                                |
| 94621 | Pulmonary stress testing; complex                                                                                                                                                                                                                                                               |
| 94640 | Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes                                                                                                                                                                 |
| 94642 | Aerosol inhalation of pentamidine for pneumocystis carinii pneumonia treatment/prophylaxis                                                                                                                                                                                                      |

|       |                                                                                                                                          |
|-------|------------------------------------------------------------------------------------------------------------------------------------------|
| 94644 | Continuous inhalation treatment w aerosol medication for acute airway obstruction; 1 <sup>st</sup> hour                                  |
| 94645 | Continuous inhalation treatment w/ aerosol medication for acute airway obstruction; ea add hr                                            |
| 94660 | Continuous positive airway pressure ventilation (CPAP), initiation and management                                                        |
| 94662 | Continuous negative pressure ventilation (CNP), initiation and management                                                                |
| 94664 | Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device           |
| 94667 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation |
| 94668 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent                              |
| 94680 | Oxygen uptake, expired gas analysis; rest and exercise, direct, simple                                                                   |
| 94681 | Oxygen uptake, expired gas analysis; including CO2 output, percentage oxygen extracted                                                   |
| 94690 | Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)                                                                 |
| 94726 | Plethysmography for determination of lung volumes and, when performed, airway resistance                                                 |
| 94727 | Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes           |
| 94728 | Airway resistance by impulse oscillometry                                                                                                |
| 94729 | Diffusing capacity (eg, carbon monoxide, membrane)                                                                                       |
| 94750 | Pulmonary compliance study (eg, plethysmography, volume and pressure measurements)                                                       |
| 94760 | Noninvasive ear or pulse oximetry for oxygen saturation; single determination                                                            |
| 94761 | Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations                                                         |
| 94762 | Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring                                              |
| 94770 | Carbon dioxide, expired gas determination by infrared analyzer                                                                           |
| 99503 | Home visit - respiratory therapy care (eg, oxygen therapy, respiratory assessment, apnea eval)                                           |
| 99504 | Home visit for mechanical ventilation care                                                                                               |

#### Oxygen Therapy – HCPCS Procedure Codes

| HCPCS | HCPCS Description                                                                                                                                                                                                                                    |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E0424 | Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                          |
| E0425 | Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                                                        |
| E0430 | Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing                                                                                                                                     |
| E0431 | Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing                                                                                                                   |
| E0433 | Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and content gauge |
| E0434 | Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing                                                                             |
| E0435 | Portable liquid oxygen system purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor                                                                             |
| E0439 | Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                                      |
| E0440 | Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator,                                                                                                                                                            |



|       |                                                                                                                                                                                             |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                                                                                    |
| E0441 | Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit                         |
| E0442 | Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit                            |
| E0443 | Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                   |
| E0444 | Portable oxygen contents, liquid (for use only with portable liquid systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                     |
| E1390 | Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate                                                     |
| E1391 | Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each                                                 |
| E1392 | Portable oxygen concentrator, rental                                                                                                                                                        |
| E1405 | Oxygen and water vapor enriching system with heated delivery                                                                                                                                |
| E1406 | Oxygen and water vapor enriching system without heated delivery                                                                                                                             |
| K0738 | Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing |
| K0741 | Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches                                   |
| S8120 | Oxygen contents, gaseous, 1 unit equals 1 cubic foot                                                                                                                                        |
| S8121 | Oxygen contents, liquid, 1 unit equals 1 pound                                                                                                                                              |

**Agents Associated with Drug-Induced Pulmonary Disease\* [Note: current list refers to DoD data; a combined DoD & HIRD list of medications will be provided.]**

| Generic Name (Alias)                         |                                                                                             |
|----------------------------------------------|---------------------------------------------------------------------------------------------|
| Study Period: 7/20/2008 to 9/30/2014         |                                                                                             |
| Product Name                                 |                                                                                             |
| Low Risk Categories                          |                                                                                             |
| <b>Antimicrobial Medications</b>             |                                                                                             |
| Ethambutol HCL                               | Ethambutol HCL<br>Myambutol                                                                 |
| Isoniazid (Isonicotinic acid hydrazide; INH) | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid<br>Nydrazid<br>Rimifon<br>Stanozide  |
| Isoniazid/Rifampin                           | Rifamate<br>Isoniazid/Rifampin                                                              |
| Isoniazid/Pyrazinamide/Rifampin              | Rifater                                                                                     |
| Minocycline                                  | Minocycline HCL<br>Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                       |
| Sulfasalazine                                | Sulfasalazine<br>Azulfidine<br>Azulfidine EN-tabs<br>Sulfazine<br>Sulfazine EC<br>S.A.S.500 |
| <b>Cardiovascular Agents</b>                 |                                                                                             |
| ACE inhibitors                               |                                                                                             |
| Benazepril HCL                               | Benazepril HCL<br>Lotensin                                                                  |
| Amlodipine Besylate/Benazepril HCL           | Amlodipine besylate/Benazepril HCL<br>Lotrel                                                |
| Captopril                                    | Captopril<br>Capoten                                                                        |
| Enalapril Maleate Oral                       | Enalapril Maleate<br>Epaned<br>Vasotec                                                      |
| Enalaprilat                                  | Enalaprilat                                                                                 |
| Enalapril Maleate/Felodipine                 | Lexxel                                                                                      |
| Enalapril Maleate/Diltiazem Malate           | Teczem                                                                                      |
| Fosinopril Sodium                            | Fosinopril Sodium<br>Monopril                                                               |
| Lisinopril                                   | Lisinopril<br>Prinivil<br>Zestril                                                           |
| Moexipril HCL                                | Moexipril HCL<br>Univasc                                                                    |

|                              |                                                                                  |
|------------------------------|----------------------------------------------------------------------------------|
| Perindopril Erbumine         | Perindopril Erbumine<br>Aceon                                                    |
| Quinapril HCL                | Quinapril HCL<br>Accupril                                                        |
| Ramipril                     | Ramipril<br>Altace                                                               |
| Trandolapril                 | Trandolapril<br>Mavik                                                            |
| Trandolapril/Verapamil HCL   | Tarka<br>Trandolapril/Verapamil HCL                                              |
| Amiodarone HCL               | Amiodarone HCL<br>Cordarone<br>Nexterone<br>Pacerone                             |
| <b>Anticoagulants</b>        |                                                                                  |
| Apixaban                     | Eliquis                                                                          |
| Dabigatran Etxilate Mesylate | Pradaxa                                                                          |
| Vorapaxar Sulfate            | Zontivity                                                                        |
| Rivaroxaban                  | Xarelto<br>Xarelto Starter Pack                                                  |
| Warfarin Sodium Oral         | Warfarin Sodium<br>Athrombin<br>Athrombin K<br>Coumadin<br>Jantoven<br>Panwarfin |
| Warfarin Potassium           | Athrombin K                                                                      |
| Ticagrelor                   | Brilinta                                                                         |
| <b>Beta Blockers</b>         |                                                                                  |
| Acebutolol HCL               | Acebutolol HCL<br>Sectral                                                        |
| Atenolol                     | Atenolol<br>Tenormin                                                             |
| Betaxolol HCL                | Betaxolol HCL<br>Kerlone                                                         |
| Bisoprolol Fumarate          | Bisoprolol Fumarate<br>Zebeta<br>Cartrol                                         |
| Carteolol HCL                | Cartrol                                                                          |
| Carvedilol                   | Carvedilol<br>Coreg                                                              |
| Carvedilol Phosphate         | Coreg CR                                                                         |
| Esmolol HCL                  | Esmolol HCL<br>Brevibloc                                                         |
| Labetalol HCL                | Labetalol HCL<br>Normodyne<br>Trandate                                           |
| Metoprolol                   |                                                                                  |
| Metoprolol Succinate         | Metoprolol Succinate<br>Toprol XL                                                |
| Metoprolol Tartrate          | Metoprolol Tartrate<br>Lopressor                                                 |
| Nadolol                      | Nadolol                                                                          |

|                                                                    |                                           |
|--------------------------------------------------------------------|-------------------------------------------|
|                                                                    | Corgard                                   |
| Nebivolol HCL                                                      | Nebivolol HCL                             |
|                                                                    | Bystolic                                  |
| Penbutolol Sulfate                                                 | Levatol                                   |
| Pindolol                                                           | Pindolol                                  |
|                                                                    | Visken                                    |
| Propranolol HCL                                                    | Propranolol HCL                           |
|                                                                    | Hemangeol                                 |
|                                                                    | Inderal LA                                |
|                                                                    | Inderal XL                                |
|                                                                    | InnoPran XL                               |
| Timolol Maleate                                                    | Timolol Maleate                           |
| Flecainide Acetate                                                 | Flecainide Acetate                        |
|                                                                    | Tambocor                                  |
| Hydralazine HCL                                                    | Hydralazine HCL                           |
|                                                                    | Dralzine                                  |
|                                                                    | Apresoline                                |
| Hydralazine/Isosorbide dinitrate                                   | BiDil                                     |
| Hydralazine/Hydrochlorothiazide/Reserpine                          | Cam-Ap-Es                                 |
|                                                                    | Hydralazine/Hydrochlorothiazide/Reserpine |
|                                                                    | Hydrap-ES                                 |
|                                                                    | Hydroserpine plus (r-h-h)                 |
|                                                                    | SER-A-GEN                                 |
|                                                                    | SER-AP-ES                                 |
| Hydralazine/Reserpine                                              | Unipres                                   |
|                                                                    | Dralserp                                  |
|                                                                    | Serpasil-Apresoline                       |
| Hydrochlorothiazide                                                | Esidrix                                   |
|                                                                    | Hydrochlorothiazide                       |
|                                                                    | Hydro-D                                   |
|                                                                    | Hydrodiuril                               |
|                                                                    | Microzide                                 |
|                                                                    | Oretic                                    |
|                                                                    | Zide                                      |
| Spirolactone/Hydrochlorothiazide                                   | Aldactazide                               |
|                                                                    | Spirolactone/Hydrochlorothiazide          |
| Methyldopa/Hydrochlorothiazide                                     | Aldoril                                   |
|                                                                    | Methyldopa/Hydrochlorothiazide            |
| Amiloride HCL/Hydrochlorothiazide                                  | Amiloride HCL/Hydrochlorothiazide         |
|                                                                    | Hydro-ride                                |
|                                                                    | Moduretic                                 |
| Amlodipine/ Valsartan/Hydrochlorothiazide                          | Amlodipine/ Valsartan/Hydrochlorothiazide |
| Aliskiren Hemifumarate/Hydrochlorothiazide                         | Tekturna HCT                              |
| Aliskiren Hemifumarate/Amlodipine Besylate/<br>Hydrochlorothiazide | Amturnide                                 |
| Candesartan Cilexetil/Hydrochlorothiazide                          | Atacand HCT                               |
|                                                                    | Candesartan Cilexetil/Hydrochlorothiazide |
| Irbesartan/Hydrochlorothiazide                                     | Avalide                                   |
|                                                                    | Irbesartan/Hydrochlorothiazide            |
| Olmesartan Medoxomil/Hydrochlorothiazide                           | Benicar HCT                               |
| Valsartan/Hydrochlorothiazide                                      | Diovan HCT                                |
|                                                                    | Valsartan/Hydrochlorothiazide             |
| Triamterene/Hydrochlorothiazide                                    | Dyazide                                   |

|                                                         |                                         |
|---------------------------------------------------------|-----------------------------------------|
| Guanethidine monosulfate/Hydrochlorothiazide            | Maxzide                                 |
| Amlodipine/Valsartan/Hydrochlorothiazide                | Triamterene/Hydrochlorothiazide         |
| Hydrochlorothiazide/Reserpine                           | Esimil                                  |
|                                                         | Exforge HCT                             |
|                                                         | H.R.-50                                 |
|                                                         | Hydro-Reserp                            |
|                                                         | Hydro-serp                              |
|                                                         | Hydropres                               |
| Losartan Potassium/Hydrochlorothiazide                  | Hyzaar                                  |
|                                                         | Losartan Potassium/Hydrochlorothiazide  |
| Telmisartan/Hydrochlorothiazide                         | Micardis HCT                            |
|                                                         | Telmisartan/Hydrochlorothiazide         |
| Deserpidine/Hydrochlorothiazide                         | Oreticyl                                |
|                                                         | Oreticyl Forte                          |
| Eprosartan Mesylate/Hydrochlorothiazide                 | Teveten HCT                             |
| Olmesartan Medoxomil / Amlodipine / Hydrochlorothiazide | Tribenzor                               |
| Procainamide HCL                                        | Procainamide HCL                        |
|                                                         | Procan                                  |
|                                                         | Procan SR                               |
|                                                         | Procanbid                               |
|                                                         | Procapan                                |
|                                                         | Pronestyl                               |
|                                                         | Pronestyl-SR                            |
| Tocainide                                               | Tonocard                                |
| <b>ACE inhibitors/ Hydrochlorothiazide</b>              |                                         |
| Benazepril HCL/Hydrochlorothiazide                      | Benazepril HCL/Hydrochlorothiazide      |
|                                                         | Lotensin HCT                            |
| Captopril/Hydrochlorothiazide                           | Captopril/Hydrochlorothiazide           |
|                                                         | Capozide                                |
| Enalapril Maleate/Hydrochlorothiazide                   | Enalapril Maleate/Hydrochlorothiazide   |
|                                                         | Vaseretic                               |
| Fosinopril Sodium//Hydrochlorothiazide                  | Fosinopril Sodium//Hydrochlorothiazide  |
|                                                         | Monopril HCT                            |
| Lisinopril/Hydrochlorothiazide                          | Lisinopril/Hydrochlorothiazide          |
|                                                         | Prinzide                                |
|                                                         | Zestoretic                              |
| Moexipril HCL/Hydrochlorothiazide                       | Moexipril HCL/Hydrochlorothiazide       |
|                                                         | Uniretic                                |
| Quinapril HCL/Hydrochlorothiazide                       | Quinapril HCL/Hydrochlorothiazide       |
|                                                         | Accuretic                               |
|                                                         | Quinaretic                              |
| <b>Beta Blockers/Thiazide Diuretics</b>                 |                                         |
| Atenolol/Chlorthalidone                                 | Atenolol/Chlorthalidone                 |
|                                                         | Tenoretic 50                            |
| Betaxolol HCL/Chlorthalidone                            | Kerledex                                |
| Bisoprolol Fumarate/Hydrochlorothiazide                 | Bisoprolol Fumarate/Hydrochlorothiazide |
|                                                         | Ziac                                    |
| Labetalol HCL/Hydrochlorothiazide                       | Normozide                               |
|                                                         | Trandate HCT                            |
| Metoprolol Succinate/Hydrochlorothiazide                | Dutoprol                                |
| Metoprolol Tartrate/Chlorthalidone                      | Lopressidone                            |
| Metoprolol Tartrate/Hydrochlorothiazide                 | Metoprolol Tartrate/Hydrochlorothiazide |

|                                     |                                     |
|-------------------------------------|-------------------------------------|
|                                     | Lopressor HCT                       |
| Nadolol/Bendroflumethiazide         | Nadolol/Bendroflumethiazide         |
|                                     | Corzide                             |
| Pindolol/Hydrochlorothiazide        | Viskazine                           |
| Propranolol HCL/Hydrochlorothiazide | Propranolol HCL/Hydrochlorothiazide |
|                                     | Inderide                            |
|                                     | Inderide LA                         |
| Timolol Maleate/Hydrochlorothiazide | Timolide 10-25                      |
| Hydralazine/Hydrochlorothiazide     | Hydra-Zide                          |
|                                     | Apresoline-Esidrix                  |
| <b>Miscellaneous</b>                |                                     |
| Phentermine HCL                     | Adipex-P                            |
|                                     | Fastin                              |
|                                     | Obestin-30                          |
|                                     | Oby-Trim                            |
|                                     | Ona-Mast                            |
|                                     | Phentermine HCL                     |
|                                     | Suprenza                            |
|                                     | Tora                                |
|                                     | Wilpo                               |

## High Risk Categories

### Anti-Inflammatory Medications

|                                  |                      |
|----------------------------------|----------------------|
| Gold                             |                      |
| Gold Sodium Thiomalate           | Myochrysine          |
| Auranofin (29% Gold)             | Ridaura              |
| Methotrexate (Amethopterin; MTX) | Methotrexate         |
|                                  | Abitrexate           |
|                                  | Folex PFS            |
|                                  | Mexate-AQ Preserved  |
|                                  | Mexate               |
|                                  | Rheumatrex Dose Pack |
|                                  | Otrexup              |
|                                  | Rasuvo               |
|                                  | Trexall              |
| Penicillamine                    | Cuprimine            |
|                                  | Depen Titratabs      |

### Monoclonal Antibodies- Antineoplastics

|             |           |
|-------------|-----------|
| Alemtuzumab | Campath   |
|             | Lemtrada  |
| Bevacizumab | Avastin   |
| Cetuximab   | Erbitux   |
| Rituximab   | Rituxan   |
| Trastuzumab | Herceptin |

### Tumor Necrosis Factor-alpha (TNFα) blockers

|                                     |                                |
|-------------------------------------|--------------------------------|
| Adalimumab                          | Humira                         |
| Certolizumab Pegol                  | Cimzia (Prefilled/Starter Kit) |
| Etanercept                          | Enbrel                         |
| Golimumab                           | Simponi                        |
|                                     | Simponi Aria                   |
| Infliximab                          | Remicade                       |
| Immune Globulin Intravenous (Human) | Bivigam                        |

Carimune NF  
Flebogamma DIF  
Gammagard S/D  
Gammagard S/D Less IgA  
Gammaplex  
Octagam

**Chemotherapeutic Agents**

|                                                     |                                                                                       |
|-----------------------------------------------------|---------------------------------------------------------------------------------------|
| Bicalutamide                                        | Bicalutamide<br>Casodex                                                               |
| Bleomycin Sulfate                                   | Bleomycin Sulfate<br>Blenoxane                                                        |
| Busulfan                                            | Busulfex<br>Myleran                                                                   |
| Carboplatin                                         | Carboplatin                                                                           |
| Capecitabine                                        | Capecitabine<br>Xeloda                                                                |
| Carmustine (BCNU)<br>Carmustine in Polifeprosan     | BiCNU<br>Gliadel Wafer                                                                |
| Chlorambucil                                        | Leukeran                                                                              |
| Cisplatin (CDDP)                                    | Cisplatin<br>Platinol                                                                 |
| Cyclophosphamide                                    | Cyclophosphamide<br>Cytosan<br>Neosar                                                 |
| Cytarabine<br>Cytarabine Liposome                   | Cytarabine<br>Cytosar-U<br>DepoCyt                                                    |
| Doxorubicin HCl                                     | Adriamycin PFS<br>Doxil (Liposomal)<br>Doxorubicin HCL<br>Doxorubicin HCL (liposomal) |
| Erlotinib                                           | Erlotinib HCL<br>Tarceva                                                              |
| Etoposide<br>Etoposide Phosphate                    | Etoposide<br>Toposar<br>VePesid<br>Etopophos                                          |
| Floxuridine                                         | Floxuridine<br>FUDR                                                                   |
| Fludarabine Phosphate                               | Fludara<br>Fludarabine Phosphate<br>Oforta                                            |
| Fluorouracil                                        | Adrucil<br>Fluorouracil                                                               |
| Flutamide                                           | Flutamide<br>Eulexin                                                                  |
| Imatinib Mesylate                                   | Gleevec                                                                               |
| Interleukin 2<br>Aldesleukin<br>Denileukin diftitox | Proleukin<br>Ontak                                                                    |
| Lomustine (CCNU)                                    | Lomustine<br>Gleostine                                                                |
| Melphalan HCL (Phenylalanine mustard)               | Melphalan HCL                                                                         |

|                                            |                                             |
|--------------------------------------------|---------------------------------------------|
|                                            | Alkeran                                     |
| Mercaptopurine                             | Mercaptopurine<br>Purinethol<br>Purixan     |
| Semustin                                   | Methyl-CCNU                                 |
| Mitomycin (Mitomycin-C; MTC)               | Mitomycin<br>Mitozytrex<br>Mutamycin        |
| Paclitaxel                                 | Abraxane<br>Paclitaxel<br>Taxol             |
| Procarbazine                               | Matulane                                    |
| Vinblastine Sulfate (VLB)                  | Vinblastine Sulfate                         |
| <b>Interferon Therapy</b>                  |                                             |
| Interferon Alfa -2B                        | Intron A                                    |
| Interferon Alfa- N3                        | Alferon N                                   |
| Interferon Alfacon-1                       | Infergen                                    |
| Interferon Beta-1A                         | Avonex<br>Rebif                             |
| Interferon Beta-1B                         | Betaseron<br>Extavia                        |
| Interferon Gamma-1B                        | Actimmune                                   |
| Peginterferon Alfa-2A                      | Pegasys                                     |
| Peginterferon Alfa-2B                      | PegIntron<br>Sylatron                       |
| Peginterferon Beta-1A                      | Plegridy                                    |
| Peginterferon alfa-2b/Ribavirin            | PegIntron and Rebetol Combo Pack            |
| <b>Miscellaneous</b>                       |                                             |
| Amphotericin B                             | Amphotericin B                              |
| Amphotericin B Lipid                       | Abelcet                                     |
| Amphotericin B Liposome                    | AmBisome                                    |
| Amphotericin B Cholesteryl Sulfate Complex | Amphotec                                    |
| Amphotericin B                             | Fungizone                                   |
| Azathioprine                               | Azathioprine<br>Azasan<br>Imuran            |
| Nitrofurantoin                             | Nitrofurantoin                              |
| Nitrofurantoin                             | Furadantin<br>Furalan                       |
| Nitrofurantoin Sodium                      | Ivadantin                                   |
| Nitrofurantoin macrocrystalline            | Nitrofurantoin Macrocrystal<br>Macrochantin |
| Nitrofurantoin monohydrate/macrocrystals   | Nitrofurantoin Monohyd Macro<br>Macrobid    |

\* Systemic use only.

## References

- Matsuno O. Drug induced interstitial lung disease: mechanisms and best diagnostic approaches. *Respir Res.* 2012;13:39.
- Schwaiblmair M, Behr W, Haeckel T, Markl B, Foerg W, Berghaus T. Drug-Induced Interstitial Lung Disease. *The Open Respiratory Medicine Journal.* 2012;6:63-74.



Fernandez AB, KarasRH, Alsheikh-AliAA, ThompsonPD. Statins and Interstitial Lung Disease. CHEST 2008; 134:824-830.

CamusP, FantonA, BonniaudP, Camus C FoucherP. Interstitial Lung Disease Induced by Drugs and Radiation. Respiration 2004;71:301-326.

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**History Of Smoking** [for sensitivity analysis]

|        |                                             |
|--------|---------------------------------------------|
| 305.1  | Tobacco Use Disorder                        |
| 649.0  | Tobacco Use Complicat Pregnancy             |
| 649.00 | Tobacco Use Comp Preg Unspecified           |
| 649.01 | Tobacco Use Comp Preg W Delivery            |
| 649.02 | Tobacco Use Comp Preg W Delivery Postpartum |
| 649.03 | Tobacco Use Comp Preg Antepartum            |
| 649.04 | Tobacco Use Comp Preg Postpartum            |
| 989.84 | Toxic Effect Tobacco                        |
| V15.82 | Personal History Of Tobacco Use             |

**Medication Proxy** (Occurrence of medication prior to index date)

|             |           |
|-------------|-----------|
| bupropion   | (Zyban)   |
| varenicline | (Chantix) |

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## **APPENDIX F. PROPENSITY SCORE MODEL DEVELOPMENT: SELECTION OF VARIABLES**

Baseline occurrence or use (i.e., one year prior to and including the Index Date).

### **Serious Liver Injury/Disease Variables:**

- Gender;
- Age;
- Year of index date (Days from start of study to patient index date: <180, 180-<360, 360-<540, 540+);
- History of Alcoholism;
- History of Bile duct disorders;
- History of Congestive heart failure;
- History of Diabetes [Diagnosis or anti-diabetic therapy];
- History of Obesity;
- Prior use of other study medication;
- Prior use of other anti-arrhythmics (other than the study medications);
- Prior use of hepatotoxic medications;
- Number of hospitalizations in acute care facilities during baseline period;
- Number of office visits during baseline period;
- Number of ER visits during baseline period;
- Number of medications (therapeutic class level) during baseline period;
- Gastroenterology / Hepatology specialty visits.

**Interstitial Lung Disease Variables:**

- Gender;
- Age;
- Year of index date (Days from start of study to patient index date: <180, 180-<360, 360-<540, 540+);
- History of Asthma;
- History of Bronchitis, exclude acute bronchitis;
- History of Chronic obstructive pulmonary disease;
- History of Connective Tissue Disease;
- History of Exposure to occupational and environmental toxins;
- History of Gastroesophageal reflux disease;
- Prior use of other study medication;
- Prior use of other anti-arrhythmics (other than the study medications);
- Prior use of agents associated with drug induced pulmonary disease:
  - Antimicrobial medications
  - Selected Cardiovascular Agents
  - Anti-Inflammatory Medications
  - Biologic Medications
  - Chemotherapy agents
  - Miscellaneous
- Prior use of Therapeutic oxygen treatment;
- Number of hospitalizations in acute care facilities during baseline period;
- Number of office visits during baseline period;
- Number of ER visits during baseline period;
- Number of medications (therapeutic class level) during baseline period;
- Pulmonology specialty visits.

Note: Self-reported information on exposure to smoking has been found to be unreliable. Therefore History of smoking will not be used as a PSM variable. However, a sensitivity analysis will be conducted, if sufficient smoking data is available to do so.

- History of Smoking; (Look at "Smoking Status" [Demographic variable], separately.)
  - Medication Proxy
    - bupropion (Zyban)
    - varenicline (Chantix)



## **APPENDIX 15. STATISTICAL ANALYSIS PLAN – DOD**



***Statistical Analysis Plan***

**Epidemiology Study**

**Serious Liver Injury and Interstitial Lung Disease Occurrences in  
Patients Diagnosed with Atrial Fibrillation Treated with Selected  
Anti-Arrhythmics**

**Study code: DRONE\_C\_05917**

Version 2

January 26, 2016

Prepared for Sanofi

By

The Degge Group, Ltd.

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## 1 Introduction and Background

Post-marketing pharmacovigilance data of spontaneous reports associated with dronedarone indicated safety signals related to serious liver injury/disease (SLD) and interstitial lung disease (ILD). In order to examine these associations in a real-world setting, where dronedarone is approved for non-permanent atrial fibrillation (AF), Sanofi requested a retrospective cohort study examining the association between exposure to dronedarone versus selected anti-arrhythmic comparator drugs and these two outcome events among adults.

This is the statistical analysis plan for an observational retrospective cohort study designed to fulfill the request.

## 2 Study Design and Objectives

### 2.1 Primary Objectives

There are two primary objectives for this study:

- Compare rates of SLD in dronedarone-exposed patients versus five separate anti-arrhythmic comparator cohorts all treated for AF.
- Compare rates of ILD in dronedarone-patients versus five separate anti-arrhythmic comparator cohorts all treated for AF.

### 2.2 General Description

An observational retrospective cohort design will be used to estimate the rates of SLD and ILD in each of two data sources. Those data sources are:

- United States Department of Defense (DoD), Military Health System electronic health record system and
- HealthCore Integrated Research Database (HIRD<sup>SM</sup>), which is a healthcare payer claims database.

(See study protocol for descriptions of the two databases.)

The two databases have structural and content differences that preclude the simple pooling of subjects or controlling for the data source. Separate analyses will therefore be conducted for each database, and results of the analyses separately reported. Unless specifically identified as applicable to only one of the outcomes or databases, all criteria and procedures described in this plan apply to the analyses of both study outcomes, in both databases.

## **2.3 Study Period**

The study start date is July 20, 2008. The study end date is September 30, 2014.

## **2.4 Study Population**

Three study populations will be identified for this study: one for the SLD analysis and two for the ILD analysis. All patients will be screened for an overall set of inclusion criteria. One set of event-specific exclusion criteria will be used to create the SLD study population. Two different sets of event-specific exclusion criteria will be applied to create the two ILD study populations. The two sets of exclusion criteria will attempt to address the multiplicity of diagnosis codes variously used to identify ILD.

## **3 Sample Size and Power Calculation**

Calculations were conducted at the outset of this study to determine the number of subjects that would be required to detect hazard ratios of 2.0, 3.0 and 4.0, for various estimated values of comparator group outcome incidence rates.

In selecting the target sample size per cohort for the study, the researchers determined that 1 event per 1,000 Person Years was a reasonably conservative estimate of the comparator incidence rate. They selected a hazard ratio of 3.0 as the effect size of importance for detection. These decisions lead to identification of 3,860 subjects as the required sample size per patient group to conduct a meaningful survival analysis for the study outcomes. (See the study protocol for background data to support the sample size and power calculations.)

## **4 Assignment of Patients to Drug Exposure Cohorts**

Exposure to any of the six anti-arrhythmic drugs listed below will be used to define the cohorts for each outcome study population:

- dronedarone;
- amiodarone;
- sotalol;
- flecainide;
- dofetilide or
- propafenone.

The first of the above-listed drugs encountered in a patient's dispensing claims history between July 20, 2009 (the dronedarone launch date in the US) and March 31, 2014 will be designated as their

**index drug** and determine their study drug cohort assignment. The date of that first index drug prescription will be the patient's **index date**. (NDC codes used to identify each study drug are found in [Appendix A.1](#) of the study protocol.)

The 365 days prior to and including the index date for each patient will be identified as their **baseline period**. Summary baseline characteristics will be reported for each of the six drug exposure cohorts.

Cohorts with fewer than the required 3,860 patients, after screening (see [sections 4.1](#) through 4.2.2) will be omitted from the propensity score matching and subsequent analyses.

#### **4.1 Screening Criteria Applied to All Patients**

After assignment to study drug cohorts, patients meeting the following criteria will be included in the outcomes study populations:

- No use of the index drug during the baseline period. Use of non-index study drugs during the baseline period is allowed;
- Prescription for only one study drug on the index date;
- Age 18 years or older as of the index date;
- Gender is not missing;
- Continuous eligibility in the health care plan (DoD or HIRD<sup>SM</sup>, as relevant) for the entire baseline period;
- At least one diagnosis of AF in the baseline period (AF identified by ICD-9-CM diagnosis code 427.31) and
- No diagnosis of cancer, organ transplant, HIV, or pregnancy (women only) during the baseline period. See [Appendix A.2](#) for the specific diagnosis codes to use for the screening applied to all patients.

#### **4.2 Additional Screening for Event Study Populations**

Patients meeting all criteria specified in [section 4.1](#) will be further screened for inclusion in one or more of the outcome event study populations.

##### **4.2.1 Additional Screening for SLD Study Population**

The SLD study population will consist of patients who pass the general screening described in [section 4.1](#), and who have no occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) during the baseline period of:

- Serious liver injury/disease event;
- History of viral hepatitis; or

- History of hereditary conditions (e.g., Wilson's disease, hemochromatosis, galactosemia, Alagille syndrome, alpha-1 antitrypsin deficiency, type 1 glycogen storage disease).

See [Appendix B.1](#) for the specific diagnosis codes to use for SLD screening.

#### 4.2.2 Additional Screening for ILD Study Populations

ILD is complex with respect to both development and diagnosis. The disease may manifest quickly or over an extended time period. Further, due to non-specific clinical presentations, a broad range of diagnoses may be assigned to ILD patients. In consideration of these complexities, a primary analysis and three sensitivity analyses (sensitivity analyses 1 – 3) will be defined for the ILD portion of the study. The four analyses will each be conducted in one of two ILD study populations, based on either a narrow or broad definition of ILD used for baseline screening (see descriptions of **ILD study population 1** and **ILD study population 2**, below).

**ILD study population 1** (narrow ILD definition) will consist of patients who pass the general screening described in [section 4.1](#), and who have no occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) during the baseline period of:

- Interstitial lung disease (narrow definition);
- Pneumonia or
- Sarcoidosis.

See [Appendix C.1](#) for the specific diagnosis codes (narrow definition) to use for ILD study population 1 screening.

**ILD study population 2** (broad ILD definition) will consist of patients who pass the general screening described in [section 4.1](#), and who have no occurrence (inpatient or outpatient) regardless of institution type (e.g., acute care hospital, skilled nursing facility, hospice, etc.) during the baseline period of:

- Interstitial lung disease (broad definition);
- Pneumonia or
- Sarcoidosis.

See [Appendix D.1](#) for the specific diagnosis codes (broad definition) to use for ILD study population 2 screening.

The primary analysis and sensitivity analysis 1 will be based on ILD study population 1 (narrow ILD definition). Sensitivity analyses 2 and 3 will be based on ILD study population 2 (broad ILD definition). (See Table 1 for the combinations of study population, event definition and risk window for each analysis.)

All four analyses will be conducted in the DOD data. Initially, only the primary analysis will be conducted in the HealthCore data. In the event that the sensitivity analyses in the DOD dataset yield significant results, then they will be replicated in the HealthCore data.

## **5 Treatment episodes, follow-up, risk periods, event identification/adjudication and event date**

### **5.1 SLD treatment episodes, follow-up, risk period, event identification / adjudication and event date**

#### **5.1.1 Treatment episodes**

A **treatment episode** will be defined as a continuous period starting on the date a study drug is dispensed, and continuing for the duration of the prescription's days' supply. In cases where there is a gap of fewer than 30 days between the date on which a prescription's days' supply ends, and the dispensing date of a subsequent prescription for the same drug, the subsequent prescription will be considered a continuation of the first treatment episode. A treatment episode ends on the date of the end of days' supply for the last prescription in the episode, plus 30 days (added as a risk window to account for potential non-compliance or missed doses). A switch treatment will occur when a different study drug is dispensed prior to the end of another treatment episode (i.e., a treatment episode for the new drug begins). In cases of a switch treatment, the end date of the first episode will be changed to the day preceding the start of the new episode. A treatment episode end date will also be changed to the earliest of date of death, end of health plan eligibility or end of study, should any of those events occur prior to the calculated end of a treatment episode. The **index treatment episode** will be the episode that begins on a patient's index date. Refer to **Figure 2** in the study protocol for a graphical description of these terms. See **SLD-Table 3** for the presentation of the numbers of unique index drug treatment episodes and numbers of non-index study drugs dispensed to patients after their index date, by study drug cohort, in the SLD study population.

#### **5.1.2 Follow-up period**

**Follow-up period** for patients in the SLD analysis begins on the day after the index date and ends at the first occurrence of end of eligibility in the health plan, death, or the end of the study period.

#### **5.1.3 Risk period**

**The SLD Risk Period** begins the day after the Index Date and continues until the earliest occurrence of an SLD event, end of eligibility in the health plan, death or the end of the index treatment episode.

#### **5.1.4 Event identification, adjudication and event date**

##### **5.1.4.1 Event identification and adjudication**

SLD will be defined by inpatient ICD-9-CM diagnosis and procedure codes, or CPT® procedure codes found in records for hospitalizations with admission dates that fall during the SLD risk period. The algorithm and hierarchy of codes is described below. Records associated with the first occurrence of any of the codes, as per the algorithm, will be selected for review by the adjudication

panel. All identified events will be considered ‘suspected,’ pending adjudication by a panel of SLD experts. Only those suspected events that receive a unanimous assessment of ‘Yes’ from the adjudicators will be counted as events for the analysis portion of the study. Adjudication of outcomes identified among patients in the Dronedarone, Sotalol, Flecainide, Dofetilide and Propafenone study drug cohorts will proceed in parallel with creation of the analysis dataset. Cases found in the Amiodarone cohort will only be forwarded for adjudication if the patient is retained in the propensity score matched analysis dataset. Since the Amiodarone cohort is the largest, by far, this two-step process will facilitate timely adjudication of cases while minimizing effort spent reviewing many that might be omitted from the final analysis. (See the study protocol for a detailed description of the actual adjudication process.)

Only hospitalizations in acute care facilities or skilled nursing facility settings will be considered for identification of SLD outcomes. In the DOD database, these hospitalizations will be defined as any that occurred in:

- A direct care facility (i.e., reported in the SIDR data table), or
- A purchased care facility (i.e., reported in the TED-I data table) coded as institution type 10 (General medical or surgical), 76 (Skilled nursing facility) or 91 (Sole community).

Two sets of codes (referenced as **Group A Codes** and **Group B Codes**) will be used to identify suspected SLD events. **Group A** diagnosis codes define an SLD event if they appear as any one of the discharge diagnoses (from the facility record) associated with an inpatient stay. **Group B** diagnosis codes only define an SLD event when they appear as the primary discharge diagnosis (from the facility record) for an inpatient stay. In all cases, the admission date of the inpatient stay with an SLD defining code must fall within the SLD risk period.

The following codes (also included as [Appendix B.2](#)) reflect liver injury/disease and will be referred to as **Group A Codes**:

**ICD-9-CM Diagnosis Codes (code must appear among the hospitalization’s discharge diagnoses, but does not need to be the Primary Discharge Diagnosis)**

570 Acute and subacute necrosis of liver

572.2 Hepatic coma

572.4 Hepatorenal syndrome

V42.7 Liver replaced by transplant

**ICD-9-CM Procedures Codes**

50.5 Liver transplant

50.51 Auxiliary liver transplant

50.59 Other transplant of liver

**CPT® Procedure Codes**

47135 Liver allotransplantation; orthotopic, partial or whole

47136 Liver allotransplantation; heterotopic, partial or whole

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The following codes (also included as [Appendix B.3](#)) reflect highly suspicious, suggestive serious liver disease and will be referred to as **Group B Codes**:

**ICD-9-CM Diagnosis Codes (code must appear as a primary discharge diagnosis):**

277.4 Disorders of bilirubin excretion  
571.5 Cirrhosis of liver without mention of alcohol  
572.8 Other sequelae of chronic liver disease  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test

**ICD-9-CM Procedure Codes**

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.91 Percutaneous aspiration of liver

**CPT® Procedure Codes**

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

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**5.1.4.2 Event Date**

The admission date of the hospitalization during which an SLD event is identified will be assigned as the event date. Patients will only be counted once as having an SLD event, regardless of subsequent SLD diagnoses or procedures.

**5.2 ILD treatment episodes, follow-up, risk periods, event identification / adjudication and event date**

**5.2.1 Treatment Episodes**

A **treatment episode** will be defined as a continuous period starting on the date a study drug is dispensed, and continuing for the duration of the prescription's days' supply. In cases where there is a gap of fewer than 30 days between the date on which a prescription's days' supply ends, and



the dispensing date of a subsequent prescription for the same drug, the subsequent prescription will be considered a continuation of the first treatment episode. A treatment episode ends on the date of the end of days' supply for the last prescription in the episode, plus 30 days (added as a risk window to account for potential non-compliance or missed doses). A switch treatment will occur when a different study drug is dispensed prior to the end of another treatment episode (i.e., a treatment episode for the new drug begins). In cases of a switch treatment, the end date of the first episode will be changed to the day preceding the start of the new episode. A treatment episode end date will also be changed to the earliest of date of death, end of health plan eligibility or end of study, should any of those events occur prior to the calculated end of a treatment episode. The **index treatment episode** will be the episode that begins on a patient's index date. Refer to **Figure 2** in the study protocol for a graphical description of these terms. See **ILD-Tables 1.3 and 2.3** for the presentation of the numbers of unique index drug treatment episodes and numbers of non-index study drugs dispensed to patients after their index date, by study drug cohort, in the two ILD study populations.

### **5.2.2 Follow-up period**

**Follow-up period** for patients in the ILD analysis begins on the day after the Index Date and ends at the first occurrence of either end of eligibility in the health plan, death, or the end of the study period.

### **5.2.3 Risk period**

**ILD Risk Period 1** is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the ILD event, end of eligibility in the health plan, death or the end of the study period.

**ILD Risk Period 2** is defined as the period that begins the day after the Index Date and continues until the earliest occurrence of the ILD event, end of eligibility in the health plan, death or the end of the index treatment episode.

### **5.2.4 Event identification, adjudication and event date**

#### **5.2.4.1 Event identification**

Two sets of diagnosis codes, corresponding to the narrow and broad definitions of ILD used for baseline screening, will be used to identify suspect events in the two ILD study populations.

Only hospitalizations in acute care facilities or skilled nursing facility settings will be considered for identification of outcomes under both the narrow and broad ILD definitions. In the DOD database, acute care hospitalizations will be defined as any that occurred in:

- A direct care facility (i.e., reported in the SIDR data table), or
- A purchased care facility (i.e., reported in the TED-I data table) coded as having occurred in an institution type 10 (General medical or surgical), 76 (Skilled nursing facility) or 91 (Sole community).

The two sets of diagnosis codes for identification of suspect ILD events are:

- The **Narrow ILD Definition** event diagnosis codes are listed below (and are also included as [Appendix C.2](#)). They will be used to identify suspect cases of ILD post-index date in ILD Study Population 1. The list includes:

**ICD-9-CM Diagnosis Codes (code must appear as a facility discharge diagnosis):**

- 515 Post-inflammatory pulmonary fibrosis
- 516.3 Idiopathic fibrosing alveolitis
  - 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
  - 516.31 Idiopathic pulmonary fibrosis (IPF)
  - 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
  - 516.33 Acute interstitial pneumonitis (AIP)
  - 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
  - 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
  - 516.36 Cryptogenic organizing pneumonia (COP)
  - 516.37 Desquamative interstitial pneumonia (DIP)
- 516.8 Other specified alveolar and parietoalveolar pneumonopathies
- 516.9 Unspecified alveolar and parietoalveolar pneumonopathy

- The **Broad ILD Definition** event diagnosis codes are listed below (and are also included as [Appendix D.2](#)). They will consist of all those in the **Narrow ILD Definition**, plus additional codes potentially indicative of ILD despite not appearing in publications included in the Mini-Sentinel review. The list includes:

**ICD-9-CM Diagnosis Codes (code must appear as a facility discharge diagnosis):**

- 495.9 Unspecified allergic alveolitis and pneumonitis
- 515 Post-inflammatory pulmonary fibrosis
- 516.3 Idiopathic fibrosing alveolitis
  - 516.30 Idiopathic interstitial pneumonia, not otherwise specified (IIP)
  - 516.31 Idiopathic pulmonary fibrosis (IPF)
  - 516.32 Idiopathic non-specific interstitial pneumonitis (NSIP)
  - 516.33 Acute interstitial pneumonitis (AIP)
  - 516.34 Respiratory bronchiolitis interstitial lung disease (RB-ILD)
  - 516.35 Idiopathic lymphoid interstitial pneumonia (LIP)
  - 516.36 Cryptogenic organizing pneumonia (COP)
  - 516.37 Desquamative interstitial pneumonia (DIP)
- 516.8 Other specified alveolar and parietoalveolar pneumonopathies
- 516.9 Unspecified alveolar and parietoalveolar pneumonopathy

## 518.82 Other pulmonary insufficiency, not elsewhere classified

ILD events used for the primary analysis and the three sensitivity analyses will vary, depending on the combination of study population, ILD event definition and the event observation risk period.

**Table 1** identifies those combinations for each analysis.

**Table 1. ILD study population, event definition and event observation risk period**

| Analysis               | ILD Study Population   | ILD Event Definition  | Risk Period   |
|------------------------|------------------------|-----------------------|---------------|
| Primary Analysis       | ILD study population 1 | ILD Narrow Definition | Risk Period 1 |
| Sensitivity Analysis 1 | ILD study population 1 | ILD Narrow Definition | Risk Period 2 |
| Sensitivity Analysis 2 | ILD study population 2 | ILD Broad Definition  | Risk Period 1 |
| Sensitivity Analysis 3 | ILD study population 2 | ILD Broad Definition  | Risk Period 2 |

### 5.2.4.2 Event Adjudication

The following procedure will be used to identify ILD events for adjudication.

#### 5.2.4.2.1 DOD Analysis

Suspected ILD events for adjudication will be separately identified from the two ILD study populations (as the two populations will use different screening and outcome definitions).

For a given patient in ILD study population 1, the first occurrence of any one of the Narrow ILD definition codes appearing as a facility discharge diagnosis during the risk period will identify a suspected event. For a given patient in ILD study population 2, the first occurrence of any one of the Broad ILD definition codes appearing as a facility discharge diagnosis during the risk period will identify a suspected event.

Suspected events associated with patients in either ILD study population 1 or ILD study population 2 will be combined into one list. Exact duplicates (i.e., same patient and event) will be removed from the combined list and information about the remaining unique events will be forwarded for adjudication. It will be possible for one patient to appear twice in the list of events for adjudication (i.e., if they are identified by a different suspect event in each of the two ILD study populations).

Only those suspected events that receive a unanimous assessment of 'Yes' from the adjudicators will be counted as events for the analysis portion of the study. Adjudication of outcomes identified among patients in the Dronedarone, Sotalol, Flecainide, Dofetilide and Propafenone study drug cohorts will proceed in parallel with creation of the analysis dataset. Cases found in the Amiodarone cohort will only be forwarded for adjudication if the patient is retained in the propensity score matched analysis dataset. Since the Amiodarone cohort is the largest, by far, this two-step process will facilitate timely adjudication of cases while minimizing effort spent reviewing many that might be omitted from the final analysis. (See the study protocol for a detailed description of the adjudication process.)

#### **5.2.4.2.2 HealthCore Analysis**

For a given patient remaining in the HealthCore ILD analysis dataset (after propensity score matching – see [section 6](#)), the first occurrence of any one of the Narrow ILD definition codes appearing as a facility discharge diagnosis during the risk period will identify a suspected event.

Information about the suspected events will be forwarded for adjudication.

Only those suspected events that receive a unanimous assessment of ‘Yes’ from the adjudicators will be counted as events for the analysis portion of the study. (See the study protocol for a detailed description of the adjudication process.)

In the event that the sensitivity analyses are also conducted in the HealthCore data (see [section 4.2.2](#)), then the event identification and adjudication will be repeated for the analysis dataset based on ILD study population 2. Unique events identified in that analysis dataset (i.e., additional events not already identified in the primary analysis dataset) will be forwarded for adjudication.

#### **5.2.4.3 Event Date**

The admission date of the hospitalization from which a confirmed event was identified will be assigned as the event date. Patients will only be counted once (in each analysis) as having an ILD outcome, regardless of subsequent ILD diagnoses.

## **6 Propensity Score Matching**

As patients in the study databases were not randomly assigned to drug treatments, confounders cannot be assumed to be balanced across cohorts. Effects of potential confounding variables in this observational study will be controlled by means of propensity score (PS) matching of control subjects not exposed to dronedarone (i.e., comparators), to the dronedarone-exposed subjects. The PS matching will adjust for the non-random nature of the observational data by creating analysis datasets of dronedarone and comparator patients who are well matched with respect to baseline characteristics.

Separate PS-matched datasets will be created for each study population (SLD, ILD population 1 and ILD population 2). Propensity scores calculation and matching will be conducted separately for each of the two distinct ILD study populations, as determined by the two baseline screening diagnosis codes definitions. The PS modeling and matching processes described below will be the same for both ILD study populations. The PS-matched dataset based on the SLD study population will be referred to as the SLD analysis dataset. The PS-matched dataset based on ILD study population 1 will be referred to as ILD analysis dataset 1. The PS-matched dataset based on ILD study population 2 will be referred to as ILD analysis dataset 2.

The following steps will be conducted to create the analysis datasets.

## **6.1 Identification of Reduced Logistic Regression Model for Calculating PS**

### **6.1.1 SLD analysis PS model**

A PS will be calculated for each SLD patient from a logistic regression model based on all patients in the SLD study population (less cases assigned to cohorts with inadequate sample size). The model will use selected baseline patient demographic data, health care utilization information, and known potential risk factors / confounders to predict treatment with dronedarone. (See [Appendix F](#) for the list of variables.)

All variables listed in [Appendix F](#) will be entered as covariates in an initial (full) logistic regression model. Backward elimination will be used in the logistic regression computations to remove variables having no association with treatment, and variables that are redundant, or nearly so, with others included in the model. The model corresponding to the step with the lowest value on the Akaike information criterion (AIC) will be assessed as optimal, and used as the final (“reduced”) model for calculation of propensity scores.

The performance of the PS logistic model will be assessed by its ability to generate matched cohort groups that are balanced with respect to the group of baseline characteristics identified in [Appendix F](#). (See [section 6.4.1](#) for a description of the balance assessment.)

### **6.1.2 ILD analysis PS model**

The process described in this section will be executed separately to develop a unique reduced PS model for each of the two ILD study populations.

A PS will be calculated for each ILD patient from a logistic regression model based on all patients in the ILD study population (less cases assigned to cohorts with inadequate sample size). The model will use selected baseline patient demographic data, health care utilization information, and known potential risk factors / confounders to predict treatment with dronedarone. (See [Appendix G](#) for the list of variables.)

All variables listed in [Appendix G](#) will be entered as covariates in an initial (full) logistic regression model. Backward elimination will be used in the logistic regression computations to remove variables having no association with treatment, and variables that are redundant, or nearly so, with others included in the model. The model corresponding to the step with the lowest value on the Akaike information criterion (AIC) will be assessed as optimal, and used as the final (“reduced”) model for calculation of propensity scores.

The performance of the PS logistic model will be assessed by its ability to generate matched cohort groups that are balanced with respect to the group of baseline characteristics identified in [Appendix G](#). (See [section 6.4.1](#) for a description of the balance assessment.)

## **6.2 Calculation of PS**

### **6.2.1 Calculation of PS for SLD analysis**

The reduced logistic regression model identified for the SLD sub-cohort (as described in [section 6.1.1](#)) will be fitted separately to subsets of the SLD sub-cohort consisting of the dronedarone cohort in combination with each one of the comparator cohorts (excluding comparator cohorts with inadequate sample size).

The log-odds of the probability predicted by the reduced logistic regression model for each patient will be used as the PS. (The log-odds is the linear portion of the value predicted by the logistic model, prior to transformation into a probability.) A PS will be calculated for patients in each subset from the version of the regression model as fitted to patients in the subset (i.e., all dronedarone patients plus one set of comparator subjects at a time). Each dronedarone patient will therefore have a distinct PS for matching to each comparator cohort.

### **6.2.2 Calculation of PS for ILD analysis**

Propensity scores will be calculated separately for the two ILD study populations. Note that there will be overlap of patients between the two ILD study populations. Patients appearing in both ILD study populations will have a distinct PS calculated for each.

The reduced logistic regression models identified for the ILD study populations (as described in [section 6.1.2](#)) will be fitted separately to subsets of the respective ILD study populations consisting of the dronedarone cohort in combination with each one of the comparator cohorts (excluding comparator cohorts with inadequate sample size).

The log-odds of the probability calculated by the reduced logistic regression model will be used as the PS. (The log-odds is the linear portion of the value predicted by the logistic model, prior to transformation into a probability.) A PS will be calculated for patients in each subset from the version of the regression model as fitted to patients in the subset (i.e., all dronedarone patients plus one set of comparator subjects at a time). Each dronedarone patient will therefore have a distinct PS for matching to each comparator cohort.

## **6.3 PS Matching**

PS matching will be conducted separately, but using the same steps, for the SLD study population and for the two ILD study populations.

### **6.3.1 Matching Schemes**

An attempt will be made to match one patient from each of the five comparator cohorts (amiodarone, sotalol, flecainide, propafenone, and dofetilide) to each patient in the dronedarone cohort according to PS. (Comparator cohorts with inadequate sample size after screening will be omitted from the matching process.) Matching will be conducted without replacement.

A nearest-neighbor-within-caliper matching algorithm will be employed. Matching will be conducted with the PS defined as the log-odds of treatment with dronedarone. The initial caliper width will be 0.2 times the standard deviation of the PS for the subset being matched<sup>1</sup>. Alternate caliper widths may also be tested for evaluation of the trade-off between sample size and covariate balance.

### **6.3.2 Matching Procedure**

As previously mentioned, only those comparator drug cohorts with sample sizes adequate to detect a hazard ratio of 3.0 will be included in the matched datasets. Matching will be conducted for one dronedarone patient at a time, beginning with the subset of patients having the smallest group of comparators. If a match is found for the dronedarone patient in the smallest comparator group, then a match will be sought for that same patient in the next smallest comparator group. Matching for a given dronedarone patient will continue in this way, through the subset of patients with the largest comparator group. Matching will be conducted as follows (see also [Figure 1](#)):

1. Calculate the standard deviation of the PS for the dronedarone and comparator patients in each subset (i.e., each combination of dronedarone patients and patients from one comparator cohort). This will be the pooled standard deviation of patients in the subset, i.e.,

8. If a match for the selected dronedarone patient is found in Step 7, then continue with Step 9. If no match is found then drop the selected dronedarone patient from the analysis. Return comparators already matched to the dropped dronedarone patient to the comparator pool (for potential matching to other dronedarone patients). Select the next dronedarone patient from the randomly sorted list created in Step 3, and repeat the matching process from Step 5.
9. If a match is found in Step 7 for the selected dronedarone patient, repeat Steps 5 through 7 for the patient subset with the next smallest number of comparators. Continue repeating Steps 5 through 9 until no comparator match for the dronedarone patient is found in a subset, or matches have been found from each comparator cohort for the selected dronedarone patient.
10. If a match is found from each comparator cohort for the selected dronedarone patient, then add the selected dronedarone patient and the matched comparator patients to the analysis dataset. Remove the selected comparator patients from the pool of potential matches for subsequent dronedarone patients.
11. Repeat Steps 5 through 10 for each subsequent patient in the randomly sorted list of dronedarone patients.
12. The final set of dronedarone patients and their comparator matches serve as the analysis dataset.

## **6.4 Sensitivity Analyses of PS Matching**

Sensitivity analyses of the datasets created with each tested combination of logistic regression model and matching caliper will be conducted to determine the effectiveness of the combination at balancing baseline characteristics across the drug cohorts, and to ensure that outcome risks do not vary systematically with the PS values.

### **6.4.1 Assessment of Baseline Covariates' Balance in PS Matched Datasets**

Standardized differences will be calculated to compare the balance of baseline covariate values between the dronedarone patients and patients in each comparator cohort (means for continuous variables and proportions for dichotomous variables) both before and after PS matching. Although it is anticipated that only a subset of the group of covariates included in the full logistic regression model will be retained in the reduced model, all covariates from the full model will be included in the comparison of baseline distributions before and after PS matching. Covariates omitted from the reduced model will be identified in the comparison table with an asterisk (\*).

While some baseline characteristics may be unbalanced prior to PS matching, the matched cohorts should display evenly balanced characteristics.

Groups will be considered well balanced if the absolute value of the standardized difference between the dronedarone group and each comparator group is less than 0.1 for all of the variables.



Any variable for which the standardized difference is >0.25 will be considered unbalanced. Imbalance after PS matching in variables listed as key risk factors (identified in [Appendix F](#) and [Appendix G](#)) will trigger refitting the PS logistic regression model and/or explicit control for the variable(s) in the survival analysis (see [section 7.3.2](#)). Imbalance after PS matching in variables not listed as key risk factors will be controlled for in the survival analysis as long as the number of imbalances does not exceed the limit of a binomial distribution test. If there are more unbalanced variables than allowed for, then the PS logistic model will be refit with data transformations or the matching will be re-run with adjustments to caliper width.

For continuous covariates, the standardized difference is defined as

$$d = \frac{(\bar{x}_{treatment} - \bar{x}_{control})}{\sqrt{\frac{s_{treatment}^2 + s_{control}^2}{2}}},$$

where

$$d = \frac{(\hat{p}_{treatment} - \hat{p}_{control})}{\sqrt{\frac{\hat{p}_{treatment}(1 - \hat{p}_{treatment}) + \hat{p}_{control}(1 - \hat{p}_{control})}{2}}},$$

Within each dronedarone – comparator subset, include the PS and a cohort \* PS interaction as covariates in the CPH analysis of the outcome. Lack of statistical significance of the coefficient associated with the interaction term (i.e., p value above 0.05) will support the conclusion that the given outcome measure does not vary systematically by PS.

## **2. Test for constancy of hazard ratio across PS quintiles, for each cohort:**

Run separate CPH analyses (see [section 7.3.2.2](#)) for the outcomes of interest for each dronedarone – comparator subset, stratified by PS quintiles. For each subset analysis, the HR should fluctuate randomly across the five PS-based strata (i.e., no systematic variation across the PS quintiles).

## **3. Plot hazard ratios and confidence intervals:**

Forest plots will be generated for visual inspection of hazard ratios and corresponding 95% confidence intervals from CPH (see [section 7.3.2.2](#)), calculated according to PS quintiles within each comparator subset. Lack of systematic variation by PS will be confirmed by no observable trend in hazard ratios, and largely overlapping confidence intervals across the quintiles.

## **6.5 Selecting Analysis Datasets**

For each outcome of interest, the dataset of PS matched cases that adequately meets the requirements of the sensitivity analyses and represents the most acceptable tradeoff between too few well-matched dronedarone cases and a large number of poorly-matched cases will be selected for use in the outcomes analyses. The study statistician will exercise judgment related to balancing the target number of patients with the targeted degree of similarity between treatment and comparison cohorts in selecting the optimum dataset for each analysis.

## **7 Reporting Results**

All results described below will be reported separately for the SLD analysis, the primary ILD analysis and each of the ILD sensitivity analyses. Where applicable, there will be separate versions of the tables for the ILD study populations and analysis datasets created using the two diagnosis codes definitions.

### **7.1 Controlling for Type-1 Errors**

In these studies the Type 1 error rate will be controlled to a 0.05 test-wise alpha level. Significance will be inferred for any analysis in which the p-value is less than 0.05 for the comparison between the dronedarone cohort and a comparator (reference) cohort. No adjustments for multiple comparisons will be applied.

### **7.2 Descriptive Summaries**

Summary tables (descriptive statistics and/or frequency tables) will be provided.

Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation, range, and median). Ninety-five percent confidence highest probability density (HPD) credible intervals may also be presented, as appropriate.

Frequency counts and percentage of subjects within each drug group per outcome will be provided for categorical data.

### 7.2.1 Baseline Characteristics

Selected baseline characteristics will be summarized for all patients eligible for inclusion in the outcome study populations, and separately for patients in the corresponding PS-matched analysis datasets. All results will be presented according to study drug cohort. The table layout and specific baseline characteristics to be reported appear in Tables **SLD-Table 1** (entire SLD study population), **SLD-Table 4** (SLD analysis dataset), **ILD-Table 1.1 and ILD-Table 2.1**, (entire ILD study population 1 and entire ILD study population 2, respectively), **ILD-Table 1.4 and ILD-Table 2.4**, (ILD analysis dataset 1 and ILD analysis dataset 2, respectively).

### 7.2.2 Follow-up Time

Numbers and proportions of patients will be reported for broad categories of follow-up time (as defined in [section 5.1.1](#)). Specific categories of follow-up time to be reported are found in **SLD-Table 2** (SLD study population), **SLD-Table 6** (SLD analysis dataset), **ILD-Tables 1.2 and 2.2**, (ILD study population 1 and ILD study population 2, respectively), and **ILD-Tables 1.6 and 2.6**, (ILD analysis dataset 1 and ILD analysis dataset 2, respectively). Follow-up time statistics will also be reported (i.e., mean, median, standard deviation, minimum and maximum).

### 7.2.3 Numbers and Proportions of Patients with Events

Numbers and proportions of patients with SLD/ILD events of interest confirmed by adjudication will be reported according to study drug cohort, along with p-values for the comparison of event proportions between dronedarone patients and each comparator drug group. Separate versions of this table will be created for patients with ILD events defined according to the four combinations of baseline screening diagnoses, event definition diagnoses and risk period definitions. Differences in proportions will be evaluated using the Fisher Exact test. Within study drug cohorts, numbers and proportions will also be reported according to:

- Patient demographic characteristics (age, gender and race), concomitant drugs, comorbidities;
- Latency periods, calculated from the index date to the outcome event date (e.g.,  $\leq 1$  month,  $> 1$  month to 6 months,  $> 6$  months exposure from the index date, as defined in [section 5.1.3](#));

Specific stratifications currently planned are listed in tables **SLD-Table 7**, **ILD-Tables 1.7 and 2.7**, (SLD, ILD 1 and ILD 2 study populations, respectively).

## 7.3 Analyses of Study Outcomes

All statistical analyses will be conducted using the PS-matched analysis datasets. Only events receiving a final decision of “Yes” by the adjudication committees will be considered. Specific analyses to be conducted are itemized below.

### 7.3.1 Incidence Rates

Incidence rates per 1,000 person years of follow-up time, and corresponding 95% confidence intervals, will be calculated by study drug cohort for each event analysis dataset (SLD, primary ILD, and ILD sensitivity analyses 1 - 3). The log-rank (Mantel-Haenszel) test will be used to test the statistical significance of differences between incidence rates of the dronedarone cohort and each of the comparator cohorts. See **SLD-Table 8** and **ILD-Tables 1.8, 1.10, 2.8, and 2.10** (ILD primary analysis and sensitivity analyses 1-3, respectively) for the proposed reporting format.

### 7.3.2 Survival Analyses

Cox proportional hazards regression and Kaplan-Meier (K-M) survival analysis will be used to examine the risk of each study outcome throughout the follow-up period for each comparator cohort versus dronedarone users (the dronedarone cohort will be the reference group in each analysis).

#### 7.3.2.1 Cox Proportional Hazards (CPH) Regression

CPH will be used to analyze the risk of each study outcome over the course of the follow-up period for each comparator cohort versus the dronedarone cohort.

Drug cohort will be the main independent variable (with dronedarone as the reference group) in these models. In the event that any baseline characteristics included in the PS model remain unbalanced between dronedarone and one or more of the comparator cohorts, models with covariates added to control for unbalanced characteristics will also be evaluated. Hazard ratios with 95% confidence intervals and corresponding p-values will be reported.

One version of the CPH analysis will be conducted for SLD, and four versions will be conducted for ILD (primary ILD and sensitivity analyses 1 - 3).

See **SLD-Table 8** and **ILD-Tables 1.8, 1.10, 2.8, and 2.10** (ILD primary analysis and sensitivity analyses 1-3, respectively) for the proposed reporting format.

##### 7.3.2.1.1 Evaluate the CPH model

For all models, Schoenfeld residuals will be examined to verify the proportionality assumption<sup>2</sup> of CPH analysis.

In addition, Harrell's C will be calculated to determine how well the model identifies patients with respect to their survival times.

The Hosmer-Lemeshow test will also be used to evaluate the predictive accuracy of the model. In this test, predicted survival probabilities at some time after follow-up (TBD based on data) will be calculated for comparison.

#### **7.3.2.2 K-M Graphs**

One K-M graph will be generated for the SLD analysis, and one each for the ILD primary analysis and the three ILD sensitivity analyses. The graphs will display separate survival curves for each study drug cohort (see sample in **Figure 2**). The log-rank (i.e., Mantel-Haenszel) test will be used to test for statistical significance of differences between the curves representing the dronedarone patients versus each of the comparator curves.

### **7.3.3 Sensitivity analysis of SLD (DoD dataset only) to addition of lab data**

A sensitivity analysis will be conducted in a subset of the SLD analysis dataset for which relevant lab test results are available to determine whether the laboratory data are a valuable addition to the clinical data with regard to the adjudicated results. Tests considered relevant to adjudication of SLD are: alanine transaminase levels, aspartate transaminase levels, and bilirubin levels [plus additional specific tests].

The value of adding the laboratory data will be assessed by having the adjudicators re-assess the subset of SLD cases, with the laboratory data also available for their review. Results from the two adjudications will be compared to assess differences in conclusions attributable to addition of the laboratory data. In the event that this reassessment of outcomes leads to changes in the adjudicated outcomes, the SLD analyses will be redone using as outcomes the cases confirmed with use of the lab data.

### **7.3.4 Sensitivity Analysis of ILD (DoD dataset only) to addition of smoking data**

A sensitivity analysis will be conducted in a subset of the ILD analysis dataset for which smoking status information is available to determine: 1) whether that subset is representative of the larger study population, and 2) whether the smoking status data are a valuable addition to the clinical data with regard to the results of the ILD events' adjudication.

The value of adding the smoking status data will be assessed by having the adjudicators re-assess events found in the subset of ILD cases, with the smoking status information also available for their review. Results from the two adjudications will be compared to assess differences in conclusions attributable to addition of the smoking status data.

## References

1. Austin PC. Optimal caliper widths for propensity-score matching when estimating differences in means and differences in proportions in observational studies. *Pharm Stat.* 2011 Mar;10(2):150-61.
2. Schoenfeld D. Chi-squared goodness-of-fit tests for the proportional hazards regression model. *Biometrika.* 1980 67(1):145-153.

## **8 Tables, Listings and Figures**

### **8.1 Tables**

**SLD-Table 1: Baseline Characteristics of Patients in the SLD Study Population according to Study Drug Cohort**

| <b>Characteristics, N (%)</b>      | <b>Dronedaronone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalolol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------------------|--------------------------------|-----------------------------|----------------------------|-----------------------------|-----------------------------|------------------------------|
| Age at cohort entry date, Mean(SD) |                                |                             |                            |                             |                             |                              |
| 18-39 years                        |                                |                             |                            |                             |                             |                              |
| 40-49 years                        |                                |                             |                            |                             |                             |                              |
| 50-59 years                        |                                |                             |                            |                             |                             |                              |
| 60-69 years                        |                                |                             |                            |                             |                             |                              |
| 70-79 years                        |                                |                             |                            |                             |                             |                              |
| 80+ years                          |                                |                             |                            |                             |                             |                              |
| Gender (female)                    |                                |                             |                            |                             |                             |                              |
| Race                               |                                |                             |                            |                             |                             |                              |
| White                              |                                |                             |                            |                             |                             |                              |
| Asian or Pacific Islander          |                                |                             |                            |                             |                             |                              |
| Black                              |                                |                             |                            |                             |                             |                              |
| American Indian/Alaskan Native     |                                |                             |                            |                             |                             |                              |
| Other                              |                                |                             |                            |                             |                             |                              |
| Unknown                            |                                |                             |                            |                             |                             |                              |
| <b>History of Disease</b>          |                                |                             |                            |                             |                             |                              |
| Deyo-Charlson Index                |                                |                             |                            |                             |                             |                              |
| Alcoholism                         |                                |                             |                            |                             |                             |                              |
| Bile Duct Disorders                |                                |                             |                            |                             |                             |                              |
| Congestive Heart Failure           |                                |                             |                            |                             |                             |                              |
| Diabetes                           |                                |                             |                            |                             |                             |                              |
| Obesity                            |                                |                             |                            |                             |                             |                              |
| <b>History of Medication Use</b>   |                                |                             |                            |                             |                             |                              |
| Other Anti-arrhythmic Agents       |                                |                             |                            |                             |                             |                              |
| Use of hepatotoxic medications     |                                |                             |                            |                             |                             |                              |



**SLD-Table 2: SLD Study Population Follow-up Time according to Study Drug Cohort**

| <b>Follow-up Time<sup>a</sup></b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|-----------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| 1 - 90 days                       |                              |                             |                          |                             |                             |                              |
| 91 - 180 days                     |                              |                             |                          |                             |                             |                              |
| 181 - 365 days                    |                              |                             |                          |                             |                             |                              |
| 366 - 545 days                    |                              |                             |                          |                             |                             |                              |
| 546 - 730 days                    |                              |                             |                          |                             |                             |                              |
| >730 days                         |                              |                             |                          |                             |                             |                              |
| Average                           |                              |                             |                          |                             |                             |                              |
| Median                            |                              |                             |                          |                             |                             |                              |
| SD                                |                              |                             |                          |                             |                             |                              |
| Min                               |                              |                             |                          |                             |                             |                              |
| Max                               |                              |                             |                          |                             |                             |                              |

<sup>a</sup>Follow-up time is calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**SLD-Table 3: SLD Study Population Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed according to Study Drug Cohort**

| <b>Drug Treatment Episodes</b>                                   | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------------------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| <b>Index Drug Treatment Episodes</b>                             |                              |                             |                          |                             |                             |                              |
| 1 Episode                                                        |                              |                             |                          |                             |                             |                              |
| 2 Episodes                                                       |                              |                             |                          |                             |                             |                              |
| 3 Episodes                                                       |                              |                             |                          |                             |                             |                              |
| 4+ Episodes                                                      |                              |                             |                          |                             |                             |                              |
| Average                                                          |                              |                             |                          |                             |                             |                              |
| Median                                                           |                              |                             |                          |                             |                             |                              |
| SD                                                               |                              |                             |                          |                             |                             |                              |
| Min                                                              |                              |                             |                          |                             |                             |                              |
| Max                                                              |                              |                             |                          |                             |                             |                              |
| <b>Number of Non-Index Study Drugs Dispensed Post Index Date</b> |                              |                             |                          |                             |                             |                              |
| 1                                                                |                              |                             |                          |                             |                             |                              |
| 2                                                                |                              |                             |                          |                             |                             |                              |
| 3                                                                |                              |                             |                          |                             |                             |                              |
| 4                                                                |                              |                             |                          |                             |                             |                              |

**SLD-Table 4: Baseline Characteristics of Patients in the SLD Analysis Dataset<sup>a</sup> according to Study Drug Cohort**

| <b>Characteristics, N (%)</b>          | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|----------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| Age at cohort entry date, Mean<br>(SD) |                              |                             |                          |                             |
| 18-39 years                            |                              |                             |                          |                             |
| 40-49 years                            |                              |                             |                          |                             |
| 50-59 years                            |                              |                             |                          |                             |
| 60-69 years                            |                              |                             |                          |                             |
| 70-79 years                            |                              |                             |                          |                             |
| 80+ years                              |                              |                             |                          |                             |
| Gender (female)                        |                              |                             |                          |                             |
| Race                                   |                              |                             |                          |                             |
| White                                  |                              |                             |                          |                             |
| Asian or Pacific Islander              |                              |                             |                          |                             |
| Black                                  |                              |                             |                          |                             |
| American Indian/Alaskan Native         |                              |                             |                          |                             |
| Other                                  |                              |                             |                          |                             |
| Unknown                                |                              |                             |                          |                             |
| <b>History of Disease</b>              |                              |                             |                          |                             |
| Deyo-Charlson Index                    |                              |                             |                          |                             |
| Alcoholism                             |                              |                             |                          |                             |
| Bile Duct Disorders                    |                              |                             |                          |                             |
| Congestive Heart Failure               |                              |                             |                          |                             |
| Diabetes                               |                              |                             |                          |                             |
| Obesity                                |                              |                             |                          |                             |
| <b>History of Medication Use</b>       |                              |                             |                          |                             |
| Other Anti-arrhythmic Agents           |                              |                             |                          |                             |
| Use of hepatotoxic medications         |                              |                             |                          |                             |

<sup>a</sup> The SLD Analysis Dataset is a PS-matched subset of the SLD Study Population.

(Note: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**SLD-Table 5: Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for SLD Study Population vs. SLD Analysis Dataset<sup>a</sup>**

| Covariates                                        | Prior to PS Matching |    |    |    |                     |     |     | PS Matched Subsets |     |     |     |                     |     |     |
|---------------------------------------------------|----------------------|----|----|----|---------------------|-----|-----|--------------------|-----|-----|-----|---------------------|-----|-----|
|                                                   | Mean Value or %      |    |    |    | 100*Difference / SD |     |     | Mean Value or %    |     |     |     | 100*Difference / SD |     |     |
|                                                   | MQ                   | AM | SO | FL | iAM                 | iSO | iFL | mMQ                | mAM | mSO | mFL | iAM                 | iSO | iFL |
| Gender (% Female)                                 |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Age on index date (mean)                          |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Days from start of study to patient Index Date    |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Alcoholism                                        |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Bile Duct Disorders                               |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Congestive Heart Failure                          |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Diabetes                                          |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Obesity                                           |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Baseline use of other study medications           |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Baseline use of other anti-arrhythmic medications |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Baseline use of hepatotoxic medications           |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Number of Hospitalizations                        |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Number of Office visits                           |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Number of ER visits                               |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Number of different medications                   |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |
| Gastroenterology specialty visits                 |                      |    |    |    |                     |     |     |                    |     |     |     |                     |     |     |

Abbreviations: MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Fecainide,

<sup>a</sup> The SLD Analysis Dataset is a PS-matched subset of the SLD Study Population.

**SLD-Table 6: SLD Analysis Dataset<sup>a</sup> Follow-up Time according to Study Drug Cohort**

| Follow-up Time <sup>b</sup> , n (%) | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------|----------------------|---------------------|------------------|---------------------|
| 1 - 90 days                         |                      |                     |                  |                     |
| 91 - 180 days                       |                      |                     |                  |                     |
| 181 - 365 days                      |                      |                     |                  |                     |
| 366 - 545 days                      |                      |                     |                  |                     |
| 546 - 730 days                      |                      |                     |                  |                     |
| >730 days                           |                      |                     |                  |                     |
| Average                             |                      |                     |                  |                     |
| Median                              |                      |                     |                  |                     |
| SD                                  |                      |                     |                  |                     |
| Min                                 |                      |                     |                  |                     |
| Max                                 |                      |                     |                  |                     |

<sup>a</sup> The SLD Analysis Dataset is a PS-matched subset of the SLD Study Population.

<sup>b</sup> Follow-up time is calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.  
(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**SLD-Table 7: SLD Analysis Dataset<sup>a</sup> Numbers and Characteristics of Patients with Adjudicated Serious Liver Injury/Disease Events**

| <b>Characteristics</b>                             | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|----------------------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| # Cases Reviewed                                   |                              |                             |                          |                             |
| Yes                                                |                              |                             |                          |                             |
| No                                                 |                              |                             |                          |                             |
| Indeterminate                                      |                              |                             |                          |                             |
| <b>Demographics</b>                                |                              |                             |                          |                             |
| Age at cohort entry date, Mean (SD)                |                              |                             |                          |                             |
| 18-39 years                                        |                              |                             |                          |                             |
| 40-49 years                                        |                              |                             |                          |                             |
| 50-59 years                                        |                              |                             |                          |                             |
| 60-69 years                                        |                              |                             |                          |                             |
| 70-79 years                                        |                              |                             |                          |                             |
| 80+ years                                          |                              |                             |                          |                             |
| Gender (female)                                    |                              |                             |                          |                             |
| Race                                               |                              |                             |                          |                             |
| White                                              |                              |                             |                          |                             |
| Asian or Pacific Islander                          |                              |                             |                          |                             |
| Black                                              |                              |                             |                          |                             |
| American Indian/Alaskan Native                     |                              |                             |                          |                             |
| Other                                              |                              |                             |                          |                             |
| Unknown                                            |                              |                             |                          |                             |
| <b>History of Disease</b>                          |                              |                             |                          |                             |
| Deyo-Charlson Index                                |                              |                             |                          |                             |
| Alcoholism                                         |                              |                             |                          |                             |
| Bile Duct Disorders                                |                              |                             |                          |                             |
| Congestive Heart Failure                           |                              |                             |                          |                             |
| Diabetes                                           |                              |                             |                          |                             |
| Obesity                                            |                              |                             |                          |                             |
| <b>History of Medication Use</b>                   |                              |                             |                          |                             |
| Other Anti-arrhythmic Agents                       |                              |                             |                          |                             |
| Hepatotoxic medications                            |                              |                             |                          |                             |
| <b>Outcome Latency from Index Date<sup>b</sup></b> |                              |                             |                          |                             |
| Up to 1 month                                      |                              |                             |                          |                             |
| 1 Month up to 6 months                             |                              |                             |                          |                             |
| Greater than 6 months                              |                              |                             |                          |                             |

<sup>a</sup> The SLD Analysis Dataset is a PS-matched subset of the SLD Study Population.

<sup>b</sup> Includes only "Yes" adjudicated outcome events.

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement and is excluded from further analysis.)

**SLD-Table 8: SLD PS-Matched Analysis Dataset<sup>a</sup> Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated Serious Liver Injury/Disease**

|                                  | Dronedarone | Amiodarone | Sotalol | Flecainide |
|----------------------------------|-------------|------------|---------|------------|
| # Cases (Yes)                    |             |            |         |            |
| # of Person-Years                |             |            |         |            |
| Incidence rate (95%CI)           |             |            |         |            |
| Crude HR (95%CI)                 | Reference   |            |         |            |
| Adjusted HR (95%CI) <sup>b</sup> | Reference   |            |         |            |

<sup>a</sup> The SLD Analysis Dataset is a PS-matched subset of the SLD Study Population.

<sup>b</sup> Adjusted for ... (if adjusted HR is calculated will specify covariates in this footnote)

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 1.1: Baseline Characteristics of Patients in ILD Study Population 1<sup>a</sup> according to Study Drug Cohort**

| <b>Characteristics</b>                                | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|-------------------------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| Age at cohort entry date, N (%)                       |                              |                             |                          |                             |                             |                              |
| 18-39 years                                           |                              |                             |                          |                             |                             |                              |
| 40-49 years                                           |                              |                             |                          |                             |                             |                              |
| 50-59 years                                           |                              |                             |                          |                             |                             |                              |
| 60-69 years                                           |                              |                             |                          |                             |                             |                              |
| 70-79 years                                           |                              |                             |                          |                             |                             |                              |
| 80+ years                                             |                              |                             |                          |                             |                             |                              |
| Gender (female)                                       |                              |                             |                          |                             |                             |                              |
| Race                                                  |                              |                             |                          |                             |                             |                              |
| White                                                 |                              |                             |                          |                             |                             |                              |
| Asian or Pacific Islander                             |                              |                             |                          |                             |                             |                              |
| Black                                                 |                              |                             |                          |                             |                             |                              |
| American Indian/Alaskan Native                        |                              |                             |                          |                             |                             |                              |
| Other                                                 |                              |                             |                          |                             |                             |                              |
| Unknown                                               |                              |                             |                          |                             |                             |                              |
| History of smoking                                    |                              |                             |                          |                             |                             |                              |
| <b>History of Disease</b>                             |                              |                             |                          |                             |                             |                              |
| Deyo-Charlson Index                                   |                              |                             |                          |                             |                             |                              |
| Asthma                                                |                              |                             |                          |                             |                             |                              |
| Bronchitis                                            |                              |                             |                          |                             |                             |                              |
| Chronic Obstructive Pulmonary Disease                 |                              |                             |                          |                             |                             |                              |
| Connective Tissue Disease                             |                              |                             |                          |                             |                             |                              |
| Exposure to Toxins                                    |                              |                             |                          |                             |                             |                              |
| Gastroesophageal Reflux Disease                       |                              |                             |                          |                             |                             |                              |
| <b>History of Medication Use</b>                      |                              |                             |                          |                             |                             |                              |
| Other Anti-arrhythmic Agents                          |                              |                             |                          |                             |                             |                              |
| Agents associated with drug-induced pulmonary disease |                              |                             |                          |                             |                             |                              |
| Therapeutic Oxygen Treatment                          |                              |                             |                          |                             |                             |                              |

<sup>a</sup> ILD Study Population 1 uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

**ILD-Table 1.2: ILD Study Population 1<sup>a</sup> Follow-up Time according to Study Drug Cohort**

| <b>Follow-up Time<sup>b</sup></b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|-----------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| 1 - 90 days                       |                              |                             |                          |                             |                             |                              |
| 91 - 180 days                     |                              |                             |                          |                             |                             |                              |
| 181 - 365 days                    |                              |                             |                          |                             |                             |                              |
| 366 - 545 days                    |                              |                             |                          |                             |                             |                              |
| 546 - 730 days                    |                              |                             |                          |                             |                             |                              |
| >730 days                         |                              |                             |                          |                             |                             |                              |
| Average                           |                              |                             |                          |                             |                             |                              |
| Median                            |                              |                             |                          |                             |                             |                              |
| SD                                |                              |                             |                          |                             |                             |                              |
| Min                               |                              |                             |                          |                             |                             |                              |
| Max                               |                              |                             |                          |                             |                             |                              |

<sup>a</sup> ILD Study Population 1 uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> Calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**ILD-Table 1.3: ILD Study Population 1<sup>a</sup> Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed according to Study Drug Cohort**

| <b>Drug Treatment<br/>Episodes</b>       | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|------------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| <b>Index Drug<br/>Treatment Episodes</b> |                              |                             |                          |                             |                             |                              |
| 1 Episode                                |                              |                             |                          |                             |                             |                              |
| 2 Episodes                               |                              |                             |                          |                             |                             |                              |
| 3 Episodes                               |                              |                             |                          |                             |                             |                              |
| 4+ Episodes                              |                              |                             |                          |                             |                             |                              |
| Average                                  |                              |                             |                          |                             |                             |                              |
| Median                                   |                              |                             |                          |                             |                             |                              |
| SD                                       |                              |                             |                          |                             |                             |                              |
| Min                                      |                              |                             |                          |                             |                             |                              |
| Max                                      |                              |                             |                          |                             |                             |                              |

**Number of Non-Index Study Drugs Dispensed Post Index Date**

1  
2  
3  
4

<sup>a</sup> ILD Study Population 1 uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).



**ILD-Table 1.4: Baseline Characteristics of Patients in ILD Analysis Dataset 1<sup>a</sup> according to Study Drug Cohort**

| Characteristics                                           | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-----------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| Age at cohort entry date, N (%)                           |                      |                     |                  |                     |
| 18-39 years                                               |                      |                     |                  |                     |
| 40-49 years                                               |                      |                     |                  |                     |
| 50-59 years                                               |                      |                     |                  |                     |
| 60-69 years                                               |                      |                     |                  |                     |
| 70-79 years                                               |                      |                     |                  |                     |
| 80+ years                                                 |                      |                     |                  |                     |
| Gender (female)                                           |                      |                     |                  |                     |
| Race                                                      |                      |                     |                  |                     |
| White                                                     |                      |                     |                  |                     |
| Asian or Pacific Islander                                 |                      |                     |                  |                     |
| Black                                                     |                      |                     |                  |                     |
| American Indian/Alaskan Native                            |                      |                     |                  |                     |
| Other                                                     |                      |                     |                  |                     |
| Unknown                                                   |                      |                     |                  |                     |
| History of smoking                                        |                      |                     |                  |                     |
| <b>History of Disease</b>                                 |                      |                     |                  |                     |
| Deyo-Charlson Index                                       |                      |                     |                  |                     |
| Asthma                                                    |                      |                     |                  |                     |
| Bronchitis                                                |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary                             |                      |                     |                  |                     |
| Connective Tissue Disease                                 |                      |                     |                  |                     |
| Exposure to Toxins                                        |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                           |                      |                     |                  |                     |
| <b>History of Medication Use</b>                          |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                              |                      |                     |                  |                     |
| Agents associated with drug-<br>induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                              |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

(Note: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 1.5: Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Study Population 1<sup>a</sup> vs. ILD PS-Matched Analysis Dataset 1<sup>b</sup>**

| Covariates                                                            | ILD Study Population 1<br>(Prior to PS Matching) |    |    |    |                     |     |     | ILD Analysis Dataset 1<br>(PS Matched Subsets) |     |     |     |                     |     |     |
|-----------------------------------------------------------------------|--------------------------------------------------|----|----|----|---------------------|-----|-----|------------------------------------------------|-----|-----|-----|---------------------|-----|-----|
|                                                                       | Mean Value or %                                  |    |    |    | 100*Difference / SD |     |     | Mean Value or %                                |     |     |     | 100*Difference / SD |     |     |
|                                                                       | MQ                                               | AM | SO | FL | iAM                 | iSO | iFL | mMQ                                            | mAM | mSO | mFL | iAM                 | iSO | iFL |
| Gender (% Female)                                                     |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Age on index date (mean)                                              |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Days from start of study to patient Index Date                        |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Asthma                                                                |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Bronchitis                                                            |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Chronic Obstructive Pulmonary Disease                                 |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Connective Tissue Disease                                             |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Exposure to Toxins                                                    |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Gastroesophageal Reflux Disease                                       |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of other study medications                               |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of other anti-arrhythmic medications                     |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of agents associated with drug induced pulmonary disease |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of therapeutic oxygen treatment                          |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of hospitalizations                                            |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of office visits                                               |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of ER visits                                                   |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of different medications                                       |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Pulmonology specialty visits                                          |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |

Abbreviations: MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Flecainide

<sup>a</sup> ILD Study Population 1 uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

**ILD-Table 1.6: ILD Analysis Dataset 1<sup>a</sup> Follow-up Time according to Study Drug Cohort**

| <b>Follow-up Time<sup>b</sup></b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|-----------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| 1 - 90 days                       |                              |                             |                          |                             |
| 91 - 180 days                     |                              |                             |                          |                             |
| 181 - 365 days                    |                              |                             |                          |                             |
| 366 - 545 days                    |                              |                             |                          |                             |
| 546 - 730 days                    |                              |                             |                          |                             |
| >730 days                         |                              |                             |                          |                             |
| Average                           |                              |                             |                          |                             |
| Median                            |                              |                             |                          |                             |
| SD                                |                              |                             |                          |                             |
| Min                               |                              |                             |                          |                             |
| Max                               |                              |                             |                          |                             |

<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> Follow-up time is calculated as time from Index Date through to the earliest of either end of eligibility, end of study or date of death.

(Note: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 1.7: ILD Analysis Dataset 1<sup>a</sup> Numbers and Characteristics of Patients with Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 1<sup>b</sup>**

| Characteristics                                       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics</b>                                   |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date<sup>c</sup></b>    |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>c</sup> Includes only "Yes" adjudicated outcome events.

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 1.8: ILD Analysis Dataset 1<sup>a</sup> Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 1<sup>b</sup>**

|                                  | Dronedarone | Amiodarone | Sotalol | Flecainide |
|----------------------------------|-------------|------------|---------|------------|
| # Cases (Yes)                    |             |            |         |            |
| # of Person-Years                |             |            |         |            |
| Incidence rate (95%CI)           |             |            |         |            |
| Crude HR (95%CI)                 | Reference   |            |         |            |
| Adjusted HR (95%CI) <sup>c</sup> | Reference   |            |         |            |

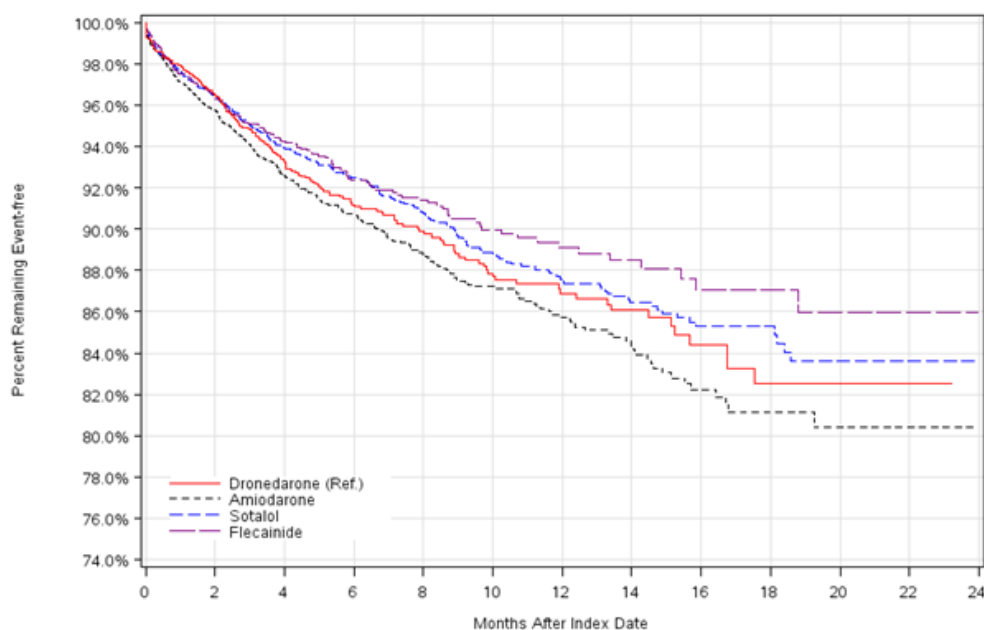
<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>c</sup> Adjusted for ... (if adjusted HR is calculated will specify covariates in this footnote)

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Figure 1.1: Sample Kaplan Meier Survival Curve ILD Analysis Dataset 1<sup>a</sup> Adjudicated Events Identified During ILD Risk Period 1<sup>b</sup>**



<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

**ILD-Table 1.9: ILD Analysis Dataset 1<sup>a</sup> Numbers and Characteristics of Patients with Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 2<sup>b</sup>**

| Characteristics                                       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics</b>                                   |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date<sup>c</sup></b>    |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>c</sup> Includes only "Yes" adjudicated outcome events.

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 1.10: ILD Analysis Dataset 1<sup>a</sup> Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 2<sup>b</sup>**

|                                  | Dronedarone | Amiodarone | Sotalol | Flecainide |
|----------------------------------|-------------|------------|---------|------------|
| # Cases (Yes)                    |             |            |         |            |
| # of Person-Years                |             |            |         |            |
| Incidence rate (95%CI)           |             |            |         |            |
| Crude HR (95%CI)                 | Reference   |            |         |            |
| Adjusted HR (95%CI) <sup>c</sup> | Reference   |            |         |            |

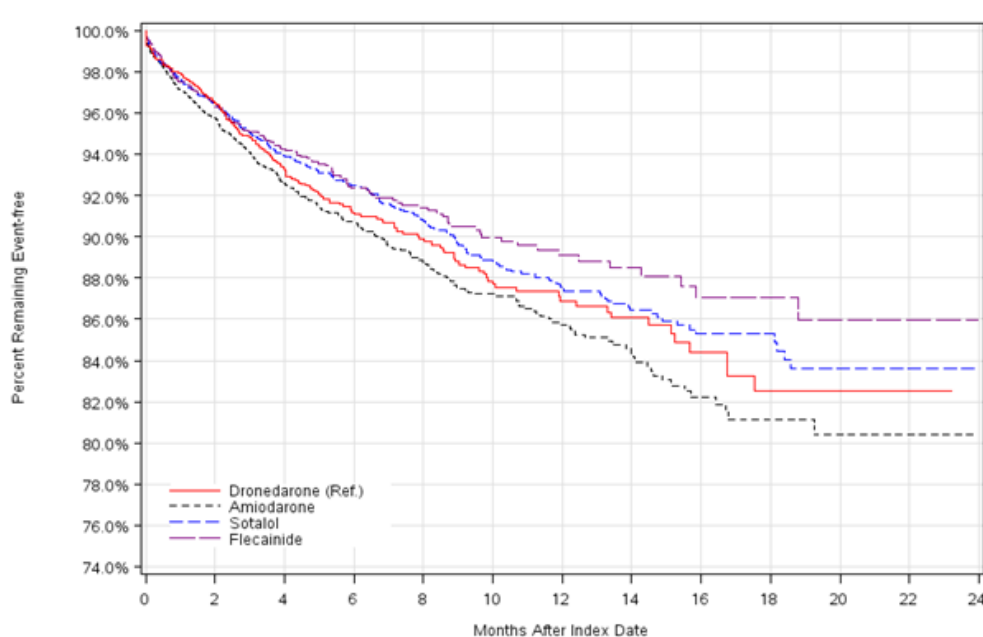
<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>c</sup> Adjusted for ... (if adjusted HR is calculated will specify covariates in this footnote)

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Figure 1.2: Sample Kaplan Meier Survival Curve ILD Analysis Dataset 1<sup>a</sup> Adjudicated Events Identified During ILD Risk Period 2<sup>b</sup>**



<sup>a</sup> ILD Analysis Dataset 1 is a PS-matched subset of ILD Study Population 1, which uses the narrow ILD definition for baseline exclusionary screening (see **Appendix C.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

**ILD-Table 2.1: Baseline Characteristics of Patients in ILD Study Population 2<sup>a</sup>  
according to Study Drug Cohort**

| Characteristics                                          | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) | Dofetilide<br>(N= ) | Propafenone<br>(N= ) |
|----------------------------------------------------------|----------------------|---------------------|------------------|---------------------|---------------------|----------------------|
| Age at cohort entry date, N (%)                          |                      |                     |                  |                     |                     |                      |
| 18-39 years                                              |                      |                     |                  |                     |                     |                      |
| 40-49 years                                              |                      |                     |                  |                     |                     |                      |
| 50-59 years                                              |                      |                     |                  |                     |                     |                      |
| 60-69 years                                              |                      |                     |                  |                     |                     |                      |
| 70-79 years                                              |                      |                     |                  |                     |                     |                      |
| 80+ years                                                |                      |                     |                  |                     |                     |                      |
| Gender (female)                                          |                      |                     |                  |                     |                     |                      |
| Race                                                     |                      |                     |                  |                     |                     |                      |
| White                                                    |                      |                     |                  |                     |                     |                      |
| Asian or Pacific Islander                                |                      |                     |                  |                     |                     |                      |
| Black                                                    |                      |                     |                  |                     |                     |                      |
| American Indian/Alaskan Native                           |                      |                     |                  |                     |                     |                      |
| Other                                                    |                      |                     |                  |                     |                     |                      |
| Unknown                                                  |                      |                     |                  |                     |                     |                      |
| History of smoking                                       |                      |                     |                  |                     |                     |                      |
| <b>History of Disease</b>                                |                      |                     |                  |                     |                     |                      |
| Deyo-Charlson Index                                      |                      |                     |                  |                     |                     |                      |
| Asthma                                                   |                      |                     |                  |                     |                     |                      |
| Bronchitis                                               |                      |                     |                  |                     |                     |                      |
| Chronic Obstructive Pulmonary Disease                    |                      |                     |                  |                     |                     |                      |
| Connective Tissue Disease                                |                      |                     |                  |                     |                     |                      |
| Exposure to Toxins                                       |                      |                     |                  |                     |                     |                      |
| Gastroesophageal Reflux Disease                          |                      |                     |                  |                     |                     |                      |
| <b>History of Medication Use</b>                         |                      |                     |                  |                     |                     |                      |
| Other Anti-arrhythmic Agents                             |                      |                     |                  |                     |                     |                      |
| Agents associated with drug-induced<br>pulmonary disease |                      |                     |                  |                     |                     |                      |
| Therapeutic Oxygen Treatment                             |                      |                     |                  |                     |                     |                      |

<sup>a</sup> ILD Study Population 2 uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).



**ILD-Table 2.2: ILD Study Population 2<sup>a</sup> Follow-up Time according to Study Drug Cohort**

| <b>Follow-up Time<sup>b</sup></b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|-----------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| 1 - 90 days                       |                              |                             |                          |                             |                             |                              |
| 91 - 180 days                     |                              |                             |                          |                             |                             |                              |
| 181 - 365 days                    |                              |                             |                          |                             |                             |                              |
| 366 - 545 days                    |                              |                             |                          |                             |                             |                              |
| 546 - 730 days                    |                              |                             |                          |                             |                             |                              |
| >730 days                         |                              |                             |                          |                             |                             |                              |
| Average                           |                              |                             |                          |                             |                             |                              |
| Median                            |                              |                             |                          |                             |                             |                              |
| SD                                |                              |                             |                          |                             |                             |                              |
| Min                               |                              |                             |                          |                             |                             |                              |
| Max                               |                              |                             |                          |                             |                             |                              |

<sup>a</sup> ILD Study Population 2 uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> Follow-up time is calculated as time from Index Date to the earliest of either end of eligibility, end of study or date of death.

**ILD-Table 2.3: ILD Study Population 2<sup>a</sup> Number of Index Drug Treatment Episodes and Number of Non-Index Study Drugs Dispensed according to Study Drug Cohort**

| <b>Drug Treatment Episodes</b>       | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> | <b>Dofetilide<br/>(N= )</b> | <b>Propafenone<br/>(N= )</b> |
|--------------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|-----------------------------|------------------------------|
| <b>Index Drug Treatment Episodes</b> |                              |                             |                          |                             |                             |                              |
| 1 Episode                            |                              |                             |                          |                             |                             |                              |
| 2 Episodes                           |                              |                             |                          |                             |                             |                              |
| 3 Episodes                           |                              |                             |                          |                             |                             |                              |
| 4+ Episodes                          |                              |                             |                          |                             |                             |                              |
| Average                              |                              |                             |                          |                             |                             |                              |
| Median                               |                              |                             |                          |                             |                             |                              |
| SD                                   |                              |                             |                          |                             |                             |                              |
| Min                                  |                              |                             |                          |                             |                             |                              |
| Max                                  |                              |                             |                          |                             |                             |                              |

**Number of Non-Index Study Drugs Dispensed Post Index Date**

1  
2  
3  
4

<sup>a</sup> ILD Study Population 2 uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

**ILD-Table 2.4: Baseline Characteristics of Patients in ILD Analysis Dataset 2<sup>a</sup> according to Study Drug Cohort**

| Characteristics                                       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary                         |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 2.5: Standardized Differences in PS Model Covariates between Dronedarone and Comparator Cohorts for ILD Study Population 2<sup>a</sup> vs. ILD Analysis Dataset 2<sup>b</sup>**

| Covariates                                                            | ILD Study Population 1<br>(Prior to PS Matching) |    |    |    |                     |     |     | ILD Analysis Dataset 1<br>(PS Matched Subsets) |     |     |     |                     |     |     |
|-----------------------------------------------------------------------|--------------------------------------------------|----|----|----|---------------------|-----|-----|------------------------------------------------|-----|-----|-----|---------------------|-----|-----|
|                                                                       | Mean Value or %                                  |    |    |    | 100*Difference / SD |     |     | Mean Value or %                                |     |     |     | 100*Difference / SD |     |     |
|                                                                       | MQ                                               | AM | SO | FL | iAM                 | iSO | iFL | mMQ                                            | mAM | mSO | mFL | iAM                 | iSO | iFL |
| Gender (% Female)                                                     |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Age on index date (mean)                                              |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Days from start of study to patient Index Date                        |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Asthma                                                                |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Bronchitis                                                            |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Chronic Obstructive Pulmonary Disease                                 |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Connective Tissue Disease                                             |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Exposure to Toxins                                                    |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Gastroesophageal Reflux Disease                                       |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of other study medications                               |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of other anti-arrhythmic medications                     |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of agents associated with drug induced pulmonary disease |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Baseline use of therapeutic oxygen treatment                          |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of hospitalizations                                            |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of office visits                                               |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of ER visits                                                   |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Number of different medications                                       |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |
| Pulmonology specialty visits                                          |                                                  |    |    |    |                     |     |     |                                                |     |     |     |                     |     |     |

Abbreviations: MQ=Dronedarone, AM=Amiodarone, SO=Sotalol, FL=Flecainide

<sup>a</sup> ILD Study Population 2 uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

**ILD-Table 2.6: ILD Analysis Dataset 2<sup>a</sup> Follow-up Time according to Study Drug Cohort**

| <b>Follow-up Time<sup>b</sup></b> | <b>Dronedarone<br/>(N= )</b> | <b>Amiodarone<br/>(N= )</b> | <b>Sotalol<br/>(N= )</b> | <b>Flecainide<br/>(N= )</b> |
|-----------------------------------|------------------------------|-----------------------------|--------------------------|-----------------------------|
| 1 - 90 days                       |                              |                             |                          |                             |
| 91 - 180 days                     |                              |                             |                          |                             |
| 181 - 365 days                    |                              |                             |                          |                             |
| 366 - 545 days                    |                              |                             |                          |                             |
| 546 - 730 days                    |                              |                             |                          |                             |
| >730 days                         |                              |                             |                          |                             |
| Average                           |                              |                             |                          |                             |
| Median                            |                              |                             |                          |                             |
| SD                                |                              |                             |                          |                             |
| Min                               |                              |                             |                          |                             |
| Max                               |                              |                             |                          |                             |

<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> Follow-up time is calculated as time from Index Date through to the earliest of either end of eligibility, end of study or date of death. Assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.

**ILD-Table 2.7: ILD Analysis Dataset 2<sup>a</sup> Numbers and Characteristics of Patients with Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 1<sup>b</sup>**

| Characteristics                                       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics</b>                                   |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date<sup>c</sup></b>    |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>c</sup> Includes only “Yes” adjudicated outcome events.

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 2.8: ILD Analysis Dataset 2<sup>a</sup> Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 1<sup>b</sup>**

|                        | Dronedarone | Amiodarone | Sotalol | Flecainide |
|------------------------|-------------|------------|---------|------------|
| # Cases (Yes)          |             |            |         |            |
| # of Person-Years      |             |            |         |            |
| Incidence rate (95%CI) |             |            |         |            |
| Crude HR (95%CI)       | Reference   |            |         |            |
| Adjusted HR (95%CI)*   | Reference   |            |         |            |

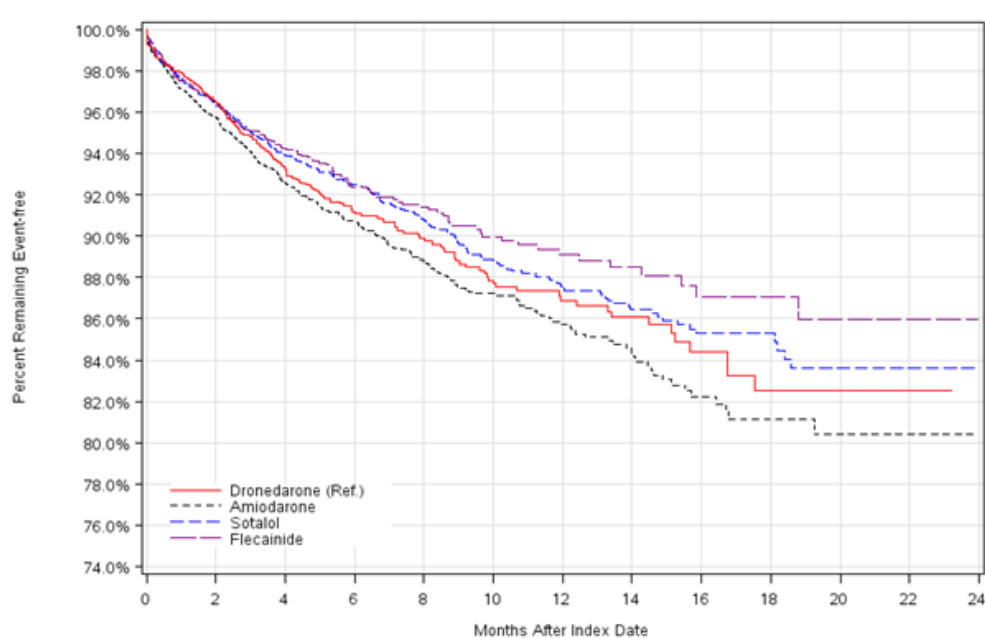
<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

<sup>c</sup> Adjusted for ... (if adjusted HR is calculated will specify covariates in this footnote)

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Figure 2.1: Sample Kaplan Meier Survival Curve ILD Analysis Dataset 2<sup>a</sup> Adjudicated Events Identified During Risk Period 1<sup>b</sup>**



<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 1 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the study period.

**ILD-Table 2.9: ILD Analysis Dataset 2<sup>a</sup> Numbers and Characteristics of Patients with Adjudicated Interstitial Lung Disease Events Identified during Risk Period 2<sup>b</sup>**

| Characteristics                                       | Dronedarone<br>(N= ) | Amiodarone<br>(N= ) | Sotalol<br>(N= ) | Flecainide<br>(N= ) |
|-------------------------------------------------------|----------------------|---------------------|------------------|---------------------|
| # Cases Reviewed                                      |                      |                     |                  |                     |
| Yes                                                   |                      |                     |                  |                     |
| No                                                    |                      |                     |                  |                     |
| Indeterminate                                         |                      |                     |                  |                     |
| <b>Demographics</b>                                   |                      |                     |                  |                     |
| Age at cohort entry date, N (%)                       |                      |                     |                  |                     |
| 18-39 years                                           |                      |                     |                  |                     |
| 40-49 years                                           |                      |                     |                  |                     |
| 50-59 years                                           |                      |                     |                  |                     |
| 60-69 years                                           |                      |                     |                  |                     |
| 70-79 years                                           |                      |                     |                  |                     |
| 80+ years                                             |                      |                     |                  |                     |
| Gender (female)                                       |                      |                     |                  |                     |
| Race                                                  |                      |                     |                  |                     |
| White                                                 |                      |                     |                  |                     |
| Asian or Pacific Islander                             |                      |                     |                  |                     |
| Black                                                 |                      |                     |                  |                     |
| American Indian/Alaskan Native                        |                      |                     |                  |                     |
| Other                                                 |                      |                     |                  |                     |
| Unknown                                               |                      |                     |                  |                     |
| History of smoking                                    |                      |                     |                  |                     |
| <b>History of Disease</b>                             |                      |                     |                  |                     |
| Deyo-Charlson Index                                   |                      |                     |                  |                     |
| Asthma                                                |                      |                     |                  |                     |
| Bronchitis                                            |                      |                     |                  |                     |
| Chronic Obstructive Pulmonary Disease                 |                      |                     |                  |                     |
| Connective Tissue Disease                             |                      |                     |                  |                     |
| Exposure to Toxins                                    |                      |                     |                  |                     |
| Gastroesophageal Reflux Disease                       |                      |                     |                  |                     |
| <b>History of Medication Use</b>                      |                      |                     |                  |                     |
| Other Anti-arrhythmic Agents                          |                      |                     |                  |                     |
| Agents associated with drug-induced pulmonary disease |                      |                     |                  |                     |
| Therapeutic Oxygen Treatment                          |                      |                     |                  |                     |
| <b>Outcome Latency from Index Date<sup>c</sup></b>    |                      |                     |                  |                     |
| Up to 1 month                                         |                      |                     |                  |                     |
| 1 Month up to 6 months                                |                      |                     |                  |                     |
| Greater than 6 months                                 |                      |                     |                  |                     |

<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>c</sup> Includes only “Yes” adjudicated outcome events.

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Table 2.10: ILD Analysis Dataset 2<sup>a</sup> Incidence Rates (per 1000 person-years) and Hazard Ratios of Adjudicated Interstitial Lung Disease Events Identified during ILD Risk Period 2<sup>b</sup>**

|                                  | Dronedarone | Amiodarone | Sotalol | Flecainide |
|----------------------------------|-------------|------------|---------|------------|
| # Cases (Yes)                    |             |            |         |            |
| # of Person-Years                |             |            |         |            |
| Incidence rate (95%CI)           |             |            |         |            |
| Crude HR (95%CI)                 | Reference   |            |         |            |
| Adjusted HR (95%CI) <sup>c</sup> | Reference   |            |         |            |

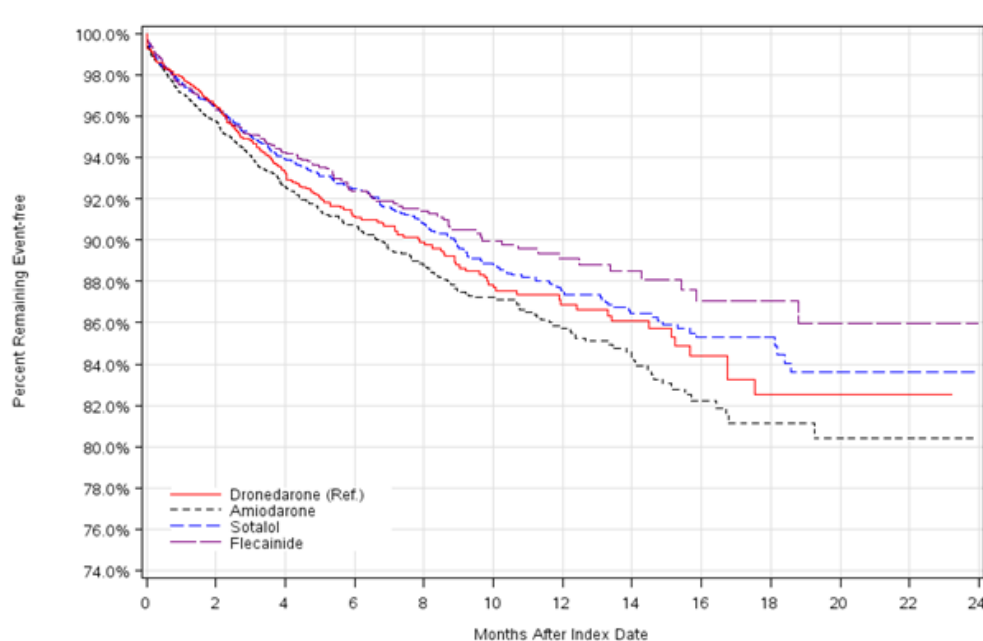
<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.

<sup>c</sup> Adjusted for ... (if adjusted HR is calculated will specify covariates in this footnote)

(NOTE: This version of the table assumes Dofetilide cohort did not meet the sample size requirement; and is excluded from further analysis.)

**ILD-Figure 2.2: Sample Kaplan Meier Survival Curve ILD Analysis Dataset 2<sup>a</sup> Adjudicated Events Identified During Risk Period 2<sup>b</sup>**



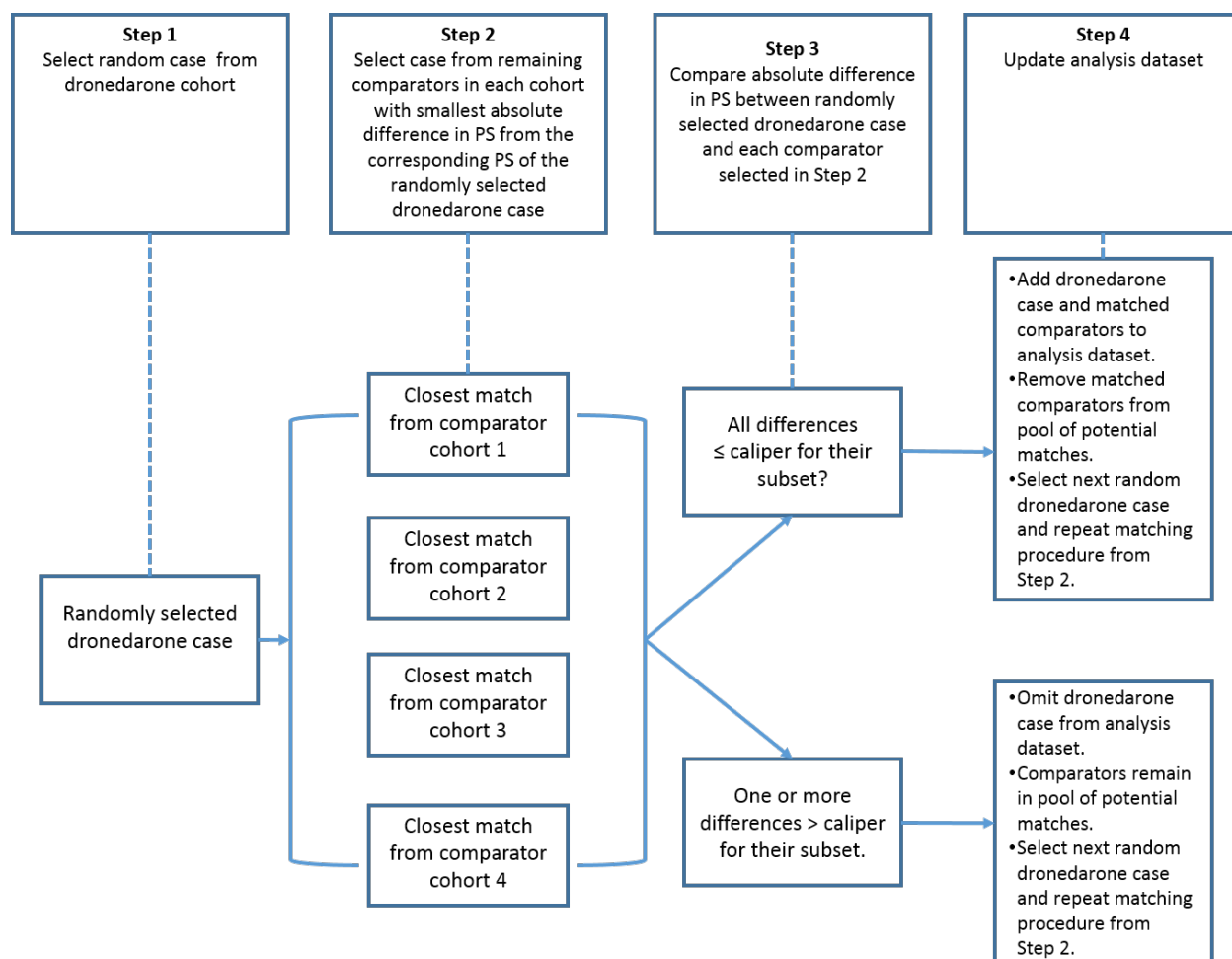
<sup>a</sup> ILD Analysis Dataset 2 is a PS-matched subset of ILD Study Population 2, which uses the broad ILD definition for baseline exclusionary screening (see **Appendix D.1**).

<sup>b</sup> ILD Risk Period 2 begins the day after the Index Date and ends at the earliest occurrence of the ILD event, end of eligibility in the health plan, death or end of the index treatment episode.



## 8.2 Figures

**Figure 1: Propensity Score Matching Process**



## 9 Appendices

## APPENDIX A.1 STUDY DRUG COHORT DEFINITIONS

### 1) Dronedarone – Multaq

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00024414210 | MULTAQ      |
| 00024414218 | MULTAQ      |
| 00024414250 | MULTAQ      |
| 00024414260 | MULTAQ      |
| 21695092060 | MULTAQ      |
| 53360414200 | MULTAQ      |
| 54868308600 | MULTAQ      |

End.

### 2) Amiodarone – Cordarone, Cordarone IV, Pacerone

| NDC         | DESCRIPTION                        |
|-------------|------------------------------------|
| 00008081401 | CORDARONE IV                       |
| 00008418802 | CORDARONE                          |
| 00008418804 | CORDARONE                          |
| 00008418806 | CORDARONE                          |
| 00074434835 | AMIODARONE HCL                     |
| 00093913306 | AMIODARONE HCL                     |
| 00093913352 | AMIODARONE HCL                     |
| 00093913393 | AMIODARONE HCL                     |
| 00143987501 | AMIODARONE HCL INJECTION, SOLUTION |
| 00143987510 | AMIODARONE HYDROCHLORIDE           |
| 00185014405 | AMIODARONE HCL                     |
| 00185014409 | AMIODARONE HCL                     |
| 00185014460 | AMIODARONE HCL                     |
| 00185014490 | AMIODARONE HCL                     |
| 00245014001 | PACERONE                           |
| 00245014030 | PACERONE                           |
| 00245014401 | PACERONE                           |
| 00245014411 | PACERONE                           |
| 00245014430 | PACERONE                           |
| 00245014489 | PACERONE                           |
| 00245014501 | PACERONE                           |
| 00245014511 | PACERONE                           |
| 00245014515 | PACERONE                           |
| 00245014530 | PACERONE                           |
| 00245014589 | PACERONE                           |
| 00245014701 | PACERONE                           |
| 00245014715 | PACERONE                           |
| 00245014760 | PACERONE                           |
| 00245014789 | PACERONE                           |
| 00245014790 | PACERONE                           |
| 00409193302 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193303 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193401 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409193411 | AMIODARONE HCL INJECTION, SOLUTION |
| 00409434835 | AMIODARONE HYDROCHLORIDE           |
| 00409434849 | NOVAPLUS AMIODARONE HYDROCHLORIDE  |
| 00548138000 | AMIODARONE HCL INJECTION           |

|             |                                    |
|-------------|------------------------------------|
| 00548138100 | AMIODARONE HCL INJECTION           |
| 00548338000 | AMIODARONE HCL                     |
| 00555091704 | AMIODARONE HCL                     |
| 00555091709 | AMIODARONE HCL                     |
| 00615454505 | AMIODARONE HCL TABLET              |
| 00615454531 | AMIODARONE HCL TABLET              |
| 00615454539 | AMIODARONE HCL TABLET              |
| 00703133201 | AMIODARONE HCL                     |
| 00703133203 | AMIODARONE HYDROCHLORIDE           |
| 00703133501 | AMIODARONE HCL                     |
| 00703133601 | AMIODARONE HCL                     |
| 00781120305 | AMIODARONE HCL                     |
| 00781120360 | AMIODARONE HCL                     |
| 00781120392 | AMIODARONE HCL                     |
| 10019013101 | AMIODARONE HCL                     |
| 10019013301 | AMIODARONE HCL                     |
| 10019013302 | AMIODARONE HCL                     |
| 10019013304 | AMIODARONE HCL                     |
| 10019013313 | AMIODARONE HCL                     |
| 10019013319 | AMIODARONE HCL                     |
| 10019013389 | AMIODARONE HCL                     |
| 10139005003 | AMIODARONE HCL                     |
| 10139005009 | AMIODARONE HCL                     |
| 10139005010 | AMIODARONE HCL                     |
| 10139005011 | AMIODARONE HCL                     |
| 10139005028 | AMIODARONE HCL                     |
| 13107005605 | AMIODARONE HYDROCHLORIDE           |
| 13107005660 | AMIODARONE HYDROCHLORIDE           |
| 17236007560 | AMIODARONE HCL                     |
| 21695079630 | AMIODARONE HCL                     |
| 21695079660 | AMIODARONE HCL                     |
| 21695079690 | AMIODARONE HCL                     |
| 25021030266 | AMIODARONE HCL INJECTION, SOLUTION |
| 25021030273 | AMIODARONE HYDROCHLORIDE           |
| 35356000110 | AMIODARONE                         |
| 35356000190 | AMIODARONE HCL                     |
| 38245013325 | AMIODARONE HCL                     |
| 38245013355 | AMIODARONE HCL                     |
| 38245013368 | AMIODARONE HCL                     |
| 38779048605 | AMIODARONE HCL                     |
| 38779048608 | AMIODARONE HCL                     |
| 43066015010 | NEXTERONE                          |
| 43066015020 | NEXTERONE                          |
| 43066036020 | NEXERONE INJECTION, SOLUTION       |
| 47463001360 | AMIODARONE HCL                     |
| 49349015402 | AMIODARONE HCL TABLET              |
| 49884045802 | AMIODARONE HCL                     |
| 49884045804 | AMIODARONE HCL                     |
| 49884045805 | AMIODARONE HCL                     |
| 51079090601 | AMIODARONE HCL                     |
| 51079090617 | AMIODARONE HYDROCHLORIDE           |
| 51079090619 | AMIODARONE HYDROCHLORIDE           |
| 51079090620 | AMIODARONE HCL                     |
| 51138049130 | AMIODARONE HCL                     |

|             |                                                 |
|-------------|-------------------------------------------------|
| 51672402503 | AMIODARONE HCL TABLET                           |
| 51672402504 | AMIODARONE HCL                                  |
| 51672405506 | AMIODARONE HCL TABLET                           |
| 51672405600 | AMIODARONE HCL TABLET                           |
| 51672405601 | AMIODARONE HCL TABLET                           |
| 51672405603 | AMIODARONE HCL TABLET                           |
| 51672405606 | AMIODARONE HCL TABLET                           |
| 51672405700 | AMIODARONE HCL                                  |
| 51672405706 | AMIODARONE HCL                                  |
| 51862015560 | AMIODARONE HCL TABLET                           |
| 51862015630 | AMIODARONE HCL TABLET                           |
| 51927376000 | AMIODARONE HYDROCHLORIDE                        |
| 52125099202 | AMIODARONE HCL TABLET                           |
| 52533010158 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52533010159 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584015303 | AMIODARONE HCL INJECTION, SOLUTION              |
| 52584034835 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 52584087501 | AMIODARONE HCL INJECTION                        |
| 53808106601 | AMIODARONE HCL TABLET                           |
| 54569176500 | CORDARONE                                       |
| 54569514000 | AMIODARONE HCL                                  |
| 54569514001 | AMIODARONE HCL                                  |
| 54569612900 | AMIODARONE HCL                                  |
| 54868461800 | AMIODARONE HCL                                  |
| 54868461801 | AMIODARONE HCL                                  |
| 54868461802 | AMIODARONE HCL                                  |
| 54868461803 | AMIODARONE HCL                                  |
| 54868518600 | PACERONE                                        |
| 54868572200 | AMIODARONE                                      |
| 55045286400 | AMIODARONE                                      |
| 55045286406 | AMIODARONE                                      |
| 55048001360 | AMIODARONE HCL                                  |
| 55154499600 | PACERONE                                        |
| 55154549200 | PACERONE                                        |
| 55154560600 | PACERONE                                        |
| 55390005701 | AMIODARONE HCL                                  |
| 55390005710 | AMIODARONE HCL                                  |
| 55390005810 | AMIODARONE HCL                                  |
| 55390009710 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 55390010501 | AMIODARONE HCL                                  |
| 55648073901 | AMIODARONE HCL INJECTION                        |
| 55648073902 | AMIODARONE HCL INJECTION                        |
| 55648073904 | AMIODARONE HCL INJECTION                        |
| 55648078001 | AMIODARONE HCL INJECTION                        |
| 55887079801 | AMIODARONE                                      |
| 55887079830 | AMIODARONE                                      |
| 55953021440 | AMIODARONE HCL                                  |
| 55953021441 | AMIODARONE HCL                                  |
| 55953021470 | AMIODARONE HCL                                  |
| 57315000901 | AMIODARONE HCL TABLET                           |
| 57315000902 | AMIODARONE HCL TABLET                           |
| 57315000904 | AMIODARONE HCL TABLET                           |
| 58016030400 | AMIODARONE                                      |
| 58016030430 | AMIODARONE                                      |

|             |                                                 |
|-------------|-------------------------------------------------|
| 58016030460 | AMIODARONE                                      |
| 58016030490 | AMIODARONE                                      |
| 60429024705 | AMIODARONE HCL                                  |
| 60429024760 | AMIODARONE HCL                                  |
| 60505072200 | AMIODARONE HCL                                  |
| 60505072201 | AMIODARONE HCL                                  |
| 60505265800 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265803 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265806 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 60505265808 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 61703024103 | AMIODARONE HCL                                  |
| 61786030931 | AMIODARONE HCL TABLET                           |
| 62086015303 | AMIODARONE HCL                                  |
| 63323061603 | AMIODARONE HYDROCHLORIDE                        |
| 63323061609 | AMIODARONE HYDROCHLORIDE                        |
| 63323061613 | AMIODARONE HYDROCHLORIDE NOVAPLUS               |
| 63739038710 | AMIODARONE HYDROCHLORIDE                        |
| 64679073901 | AMIODARONE HCL INJECTION                        |
| 64679073902 | AMIODARONE HCL INJECTION                        |
| 64679078001 | AMIODARONE HCL INJECTION                        |
| 65084045618 | PACERONE                                        |
| 65084045620 | PACERONE                                        |
| 65841063105 | AMIODARONE HCL TABLET                           |
| 65841063106 | AMIODARONE HCL TABLET                           |
| 65841063110 | AMIODARONE HCL TABLET                           |
| 65841063114 | AMIODARONE HCL TABLET                           |
| 65841063130 | AMIODARONE HCL TABLET                           |
| 67457015300 | AMIODARONE HCL INJECTION, SOLUTION, CONCENTRATE |
| 67457015303 | AMIODARONE HCL                                  |
| 67457015309 | AMIODARONE HYDROCHLORIDE                        |
| 67457015318 | AMIODARONE HYDROCHLORIDE                        |
| 67544017630 | AMIODARONE HCL                                  |
| 67544057030 | PACERONE                                        |
| 68084037101 | AMIODARONE HYDROCHLORIDE                        |
| 68084037111 | AMIODARONE HCL                                  |
| 68382022705 | AMIODARONE HYDROCHLORIDE                        |
| 68382022706 | AMIODARONE HCL TABLET                           |
| 68382022710 | AMIODARONE HCL TABLET                           |
| 68382022714 | AMIODARONE HYDROCHLORIDE                        |
| 68382022730 | AMIODARONE HCL TABLET                           |
| 68382022777 | AMIODARONE HCL TABLET                           |
| 76237010830 | AMIODARONE HCL TABLET                           |

End.

### 3) Sotalol – Betapace, Betapace AF, Sorine, Sorine AF

| NDC         | DESCRIPTION    |
|-------------|----------------|
| 00093106001 | SOTALOL HCL    |
| 00093106101 | SOTALOL HCL    |
| 00093106201 | SOTALOL HCL    |
| 00093106301 | SOTALOL HCL    |
| 00093740106 | SOTALOL HCL AF |
| 00093740206 | SOTALOL HCL AF |
| 00093740306 | SOTALOL HCL AF |
| 00115271101 | SOTALOL HCL    |
| 00115271102 | SOTALOL HCL    |
| 00115271103 | SOTALOL HCL    |
| 00115272201 | SOTALOL HCL    |
| 00115272202 | SOTALOL HCL    |
| 00115272203 | SOTALOL HCL    |
| 00115273301 | SOTALOL HCL    |
| 00115273302 | SOTALOL HCL    |
| 00115273303 | SOTALOL HCL    |
| 00115274401 | SOTALOL HCL    |
| 00115274402 | SOTALOL HCL    |
| 00115274403 | SOTALOL HCL    |
| 00185017001 | SOTALOL HCL    |
| 00185017005 | SOTALOL HCL    |
| 00185017009 | SOTALOL HCL    |
| 00185017101 | SOTALOL HCL    |
| 00185017105 | SOTALOL HCL    |
| 00185017109 | SOTALOL HCL    |
| 00185017401 | SOTALOL HCL    |
| 00185017405 | SOTALOL HCL    |
| 00185017409 | SOTALOL HCL    |
| 00185017701 | SOTALOL HCL    |
| 00185017705 | SOTALOL HCL    |
| 00185017709 | SOTALOL HCL    |
| 00245001201 | SORINE         |
| 00245001211 | SORINE         |
| 00245001289 | SORINE         |
| 00245001301 | SORINE         |
| 00245001311 | SORINE         |
| 00245001389 | SORINE         |
| 00245001401 | SORINE         |
| 00245001411 | SORINE         |
| 00245001489 | SORINE         |
| 00245001501 | SORINE         |
| 00245001511 | SORINE         |
| 00245001589 | SORINE         |
| 00378030501 | SOTALOL HCL    |
| 00378031001 | SOTALOL HCL    |
| 00378031401 | SOTALOL HCL    |
| 00378512301 | SOTALOL HCL    |
| 00378512401 | SOTALOL HCL    |
| 00378512501 | SOTALOL HCL    |
| 00440836030 | SOTALOL HCL    |
| 00440836060 | SOTALOL HCL    |
| 00440836090 | SOTALOL HCL    |
| 00440836091 | SOTALOL HCL    |
| 00440836130 | SOTALOL HCL    |
| 00440836160 | SOTALOL HCL    |
| 00440836190 | SOTALOL HCL    |

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|             |                   |
|-------------|-------------------|
| 00440836191 | SOTALOL HCL       |
| 00440836230 | SOTALOL HCL       |
| 00440836260 | SOTALOL HCL       |
| 00440836290 | SOTALOL HCL       |
| 00440836291 | SOTALOL HCL       |
| 00603576910 | SOTALOL HCL       |
| 00603576921 | SOTALOL HCL       |
| 00603576928 | SOTALOL HCL       |
| 00603576929 | SOTALOL HCL       |
| 00603576932 | SOTALOL HCL       |
| 00603577010 | SOTALOL HCL       |
| 00603577021 | SOTALOL HCL       |
| 00603577025 | SOTALOL HCL       |
| 00603577028 | SOTALOL HCL       |
| 00603577029 | SOTALOL HCL       |
| 00603577032 | SOTALOL HCL       |
| 00603577110 | SOTALOL HCL       |
| 00603577121 | SOTALOL HCL       |
| 00603577128 | SOTALOL HCL       |
| 00603577129 | SOTALOL HCL       |
| 00603577132 | SOTALOL HCL       |
| 00603577221 | SOTALOL HCL       |
| 00603577228 | SOTALOL HCL       |
| 00603577229 | SOTALOL HCL       |
| 00677170901 | SOTALOL HCL       |
| 00677170905 | SOTALOL HCL       |
| 00677170906 | SOTALOL HCL       |
| 00677170907 | SOTALOL HCL       |
| 00677171001 | SOTALOL HCL       |
| 00677171005 | SOTALOL HCL       |
| 00677171006 | SOTALOL HCL       |
| 00677171101 | SOTALOL HCL       |
| 00677171105 | SOTALOL HCL       |
| 00677171106 | SOTALOL HCL       |
| 00677171201 | SOTALOL HCL       |
| 00677171205 | SOTALOL HCL       |
| 00677171206 | SOTALOL HCL       |
| 00677171207 | SOTALOL HCL       |
| 00677189301 | SOTALOL HCL AF    |
| 00677189306 | SOTALOL HCL AF    |
| 00677189401 | SOTALOL HCL AF    |
| 00677189406 | SOTALOL HCL AF    |
| 00677189501 | SOTALOL HCL AF    |
| 00677189506 | SOTALOL HCL AF    |
| 15330020801 | SOTALOL HCL       |
| 15330020901 | SOTALOL HCL       |
| 15330021001 | SOTALOL HCL       |
| 21695039730 | SOTALOL           |
| 24338053025 | SOTYLIZE SOLUTION |
| 24338053048 | SOTYLIZE SOLUTION |
| 35356093530 | SOTALOL HCL       |
| 35356093560 | SOTALOL HCL       |
| 35356093590 | SOTALOL HCL       |
| 35356096430 | SOTALOL HCL       |
| 35356096460 | SOTALOL HCL       |
| 35356096490 | SOTALOL HCL       |
| 42291076001 | SOTALOL HCL       |
| 42291076101 | SOTALOL HCL       |
| 42291076201 | SOTALOL HCL       |

|             |                |
|-------------|----------------|
| 43063013330 | SOTALOL HCL    |
| 47463077830 | SOTALOL HCL AF |
| 47463077930 | SOTALOL HCL AF |
| 49884058201 | SOTALOL HCL    |
| 49884058210 | SOTALOL HCL    |
| 49884058301 | SOTALOL HCL    |
| 49884058310 | SOTALOL HCL    |
| 49884058401 | SOTALOL HCL    |
| 49884058410 | SOTALOL HCL    |
| 49884058501 | SOTALOL HCL    |
| 49884058510 | SOTALOL HCL    |
| 50419010510 | BETAPACE       |
| 50419010511 | BETAPACE       |
| 50419010610 | BETAPACE       |
| 50419010611 | BETAPACE       |
| 50419010710 | BETAPACE       |
| 50419010711 | BETAPACE       |
| 50419010910 | BETAPACE       |
| 50419010911 | BETAPACE       |
| 50419011506 | BETAPACE AF    |
| 50419011511 | BETAPACE AF    |
| 50419011606 | BETAPACE AF    |
| 50419011611 | BETAPACE AF    |
| 50419011906 | BETAPACE AF    |
| 50419011911 | BETAPACE AF    |
| 51138056130 | SOTALOL HCL    |
| 51138056230 | SOTALOL HCL    |
| 51138056330 | SOTALOL HCL    |
| 51138056430 | SOTALOL HCL    |
| 52544065401 | SOTALOL HCL    |
| 52544065501 | SOTALOL HCL    |
| 52544065601 | SOTALOL HCL    |
| 52544066501 | SOTALOL HCL    |
| 53217001190 | SOTALOL HCL    |
| 53489028801 | SOTALOL HCL    |
| 53489028802 | SOTALOL HCL    |
| 53489028803 | SOTALOL HCL    |
| 53489028805 | SOTALOL HCL    |
| 53489028810 | SOTALOL HCL    |
| 53489028901 | SOTALOL HCL    |
| 53489028902 | SOTALOL HCL    |
| 53489028903 | SOTALOL HCL    |
| 53489028905 | SOTALOL HCL    |
| 53489028910 | SOTALOL HCL    |
| 53489029001 | SOTALOL HCL    |
| 53489029002 | SOTALOL HCL    |
| 53489029003 | SOTALOL HCL    |
| 53489029005 | SOTALOL HCL    |
| 53489029010 | SOTALOL HCL    |
| 53489029101 | SOTALOL HCL    |
| 53489029102 | SOTALOL HCL    |
| 53489029103 | SOTALOL HCL    |
| 53489029105 | SOTALOL HCL    |
| 53489029110 | SOTALOL HCL    |
| 53489050301 | SOTALOL        |
| 53489050303 | SOTALOL        |
| 53489050305 | SOTALOL        |
| 53489050306 | SOTALOL        |
| 53489050307 | SOTALOL        |

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|             |                |
|-------------|----------------|
| 53489050310 | SOTALOL        |
| 53489050401 | SOTALOL        |
| 53489050403 | SOTALOL        |
| 53489050405 | SOTALOL        |
| 53489050406 | SOTALOL        |
| 53489050407 | SOTALOL        |
| 53489050410 | SOTALOL        |
| 53489050501 | SOTALOL        |
| 53489050503 | SOTALOL        |
| 53489050505 | SOTALOL        |
| 53489050506 | SOTALOL        |
| 53489050507 | SOTALOL        |
| 53489050510 | SOTALOL        |
| 54569443400 | BETAPACE       |
| 54569443500 | BETAPACE       |
| 54868442300 | BETAPACE AF    |
| 54868442301 | BETAPACE AF    |
| 54868443500 | SOTALOL HCL    |
| 54868443501 | SOTALOL HCL    |
| 54868443502 | SOTALOL HCL    |
| 54868443503 | SOTALOL HCL    |
| 54868554900 | SOTALOL HCL    |
| 54868554901 | SOTALOL HCL    |
| 54868561400 | SOTALOL HCL    |
| 54868561401 | SOTALOL HCL AF |
| 55045316000 | SOTALOL HCL    |
| 55048077830 | SOTALOL HCL AF |
| 55048077930 | SOTALOL HCL AF |
| 57866903201 | SOTALOL HCL    |
| 57866903202 | SOTALOL HCL    |
| 57866903203 | SOTALOL HCL    |
| 57866903204 | SOTALOL HCL    |
| 57866903301 | SOTALOL HCL    |
| 57866903302 | SOTALOL HCL    |
| 57866903303 | SOTALOL HCL    |
| 57866903304 | SOTALOL HCL    |
| 57866903401 | SOTALOL HCL    |
| 57866903402 | SOTALOL HCL    |
| 57866903403 | SOTALOL HCL    |
| 57866903404 | SOTALOL HCL    |
| 58016018800 | SOTALOL HCL    |
| 58016018802 | SOTALOL HCL    |
| 58016018830 | SOTALOL HCL    |
| 58016018860 | SOTALOL HCL    |
| 58016018890 | SOTALOL HCL    |
| 60429039001 | SOTALOL HCL    |
| 60429039060 | SOTALOL HCL    |
| 60429039101 | SOTALOL HCL    |
| 60429039160 | SOTALOL HCL    |
| 60429039201 | SOTALOL HCL    |
| 60429039260 | SOTALOL HCL    |
| 60429074801 | SOTALOL HCL    |
| 60429074901 | SOTALOL HCL    |
| 60429075001 | SOTALOL HCL    |
| 60429075101 | SOTALOL HCL    |
| 60429094801 | SOTALOL HCL    |
| 60429094901 | SOTALOL HCL    |
| 60429095001 | SOTALOL HCL    |
| 60429095101 | SOTALOL HCL    |

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|             |                |
|-------------|----------------|
| 60505008000 | SOTALOL HCL    |
| 60505008010 | SOTALOL HCL    |
| 60505008100 | SOTALOL HCL    |
| 60505008110 | SOTALOL HCL    |
| 60505008200 | SOTALOL HCL    |
| 60505008201 | SOTALOL HCL    |
| 60505015900 | SOTALOL HCL    |
| 60505022201 | SOTALOL HCL AF |
| 60505022210 | SOTALOL HCL    |
| 60505022220 | SOTALOL HCL    |
| 60505022301 | SOTALOL HCL AF |
| 60505022310 | SOTALOL HCL    |
| 60505022320 | SOTALOL HCL    |
| 60505022401 | SOTALOL HCL AF |
| 60505022410 | SOTALOL HCL    |
| 60505022420 | SOTALOL HCL    |
| 62451010510 | SOTALOL HCL    |
| 62451010610 | SOTALOL HCL    |
| 62451010710 | SOTALOL HCL    |
| 62451010910 | SOTALOL HCL    |
| 63629471910 | SOTALOL HCL    |
| 63629472010 | SOTALOL HCL    |
| 63629472020 | SOTALOL HCL    |
| 65162072510 | SOTALOL HCL    |
| 65162072710 | SOTALOL HCL    |
| 65162073110 | SOTALOL HCL    |
| 67457017610 | SOTALOL HCL    |
| 68084038701 | SOTALOL HCL    |
| 68084038711 | SOTALOL HCL    |
| 68084049701 | SOTALOL HCL    |
| 68084049711 | SOTALOL HCL    |
| 68084065401 | SOTALOL HCL    |
| 68084065411 | SOTALOL HCL    |
| 68115066100 | SOTALOL HCL    |
| 68151270290 | SOTALOL HCL    |

End.

#### 4) Flecainide – Tambocor

| NDC         | DESCRIPTION        |
|-------------|--------------------|
| 00054001020 | FLECAINIDE ACETATE |
| 00054001021 | FLECAINIDE ACETATE |
| 00054001025 | FLECAINIDE ACETATE |
| 00054001120 | FLECAINIDE ACETATE |
| 00054001121 | FLECAINIDE ACETATE |
| 00054001125 | FLECAINIDE ACETATE |
| 00054001220 | FLECAINIDE ACETATE |
| 00054001221 | FLECAINIDE ACETATE |
| 00054001225 | FLECAINIDE ACETATE |
| 00089030510 | TAMBOCOR           |
| 00089030516 | TAMBOCOR           |
| 00089030710 | TAMBOCOR           |
| 00089030716 | TAMBOCOR           |
| 00089031410 | TAMBOCOR           |
| 00089031416 | TAMBOCOR           |
| 00378850501 | FLECAINIDE ACETATE |
| 00378851001 | FLECAINIDE ACETATE |
| 00378851501 | FLECAINIDE ACETATE |
| 00440754260 | FLECAINIDE ACETATE |
| 00440754360 | FLECAINIDE ACETATE |
| 00440754460 | FLECAINIDE ACETATE |
| 00555085902 | FLECAINIDE ACETATE |
| 00555086002 | FLECAINIDE ACETATE |
| 00555086102 | FLECAINIDE ACETATE |
| 00781506201 | FLECAINIDE ACETATE |
| 00781506301 | FLECAINIDE ACETATE |
| 00781506401 | FLECAINIDE ACETATE |
| 12280018230 | TAMBOCOR           |
| 29336030510 | TAMBOCOR           |
| 29336030710 | TAMBOCOR           |
| 29336031410 | TAMBOCOR           |
| 29366031410 | TAMBOCOR           |
| 49884069401 | FLECAINIDE ACETATE |
| 49884069501 | FLECAINIDE ACETATE |
| 49884069601 | FLECAINIDE ACETATE |
| 50268032011 | FLECAINIDE ACETATE |
| 50268032015 | FLECAINIDE ACETATE |
| 50268032111 | FLECAINIDE ACETATE |
| 50268032115 | FLECAINIDE ACETATE |
| 50268032211 | FLECAINIDE ACETATE |
| 50268032215 | FLECAINIDE ACETATE |
| 51079098701 | FLECAINIDE ACETATE |
| 51079098720 | FLECAINIDE ACETATE |
| 51079098820 | FLECAINIDE ACETATE |
| 54569050000 | TAMBOCOR           |
| 54569613100 | FLECAINIDE ACETATE |
| 54569613200 | FLECAINIDE ACETATE |
| 54868440700 | TAMBOCOR           |
| 54868506500 | TAMBOCOR           |
| 54868506501 | TAMBOCOR           |
| 54868507400 | FLECAINIDE ACETATE |
| 54868507401 | FLECAINIDE ACETATE |
| 54868507402 | FLECAINIDE ACETATE |
| 54868507403 | FLECAINIDE ACETATE |
| 54868540500 | FLECAINIDE ACETATE |
| 54868540501 | FLECAINIDE ACETATE |

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|             |                    |
|-------------|--------------------|
| 54868558600 | FLECAINIDE         |
| 54868558601 | FLECAINIDE ACETATE |
| 55045381901 | FLECAINIDE ACETATE |
| 58016096202 | FLECAINIDE ACETATE |
| 58016096203 | FLECAINIDE ACETATE |
| 58016096204 | FLECAINIDE ACETATE |
| 58016096230 | FLECAINIDE ACETATE |
| 58016096240 | FLECAINIDE ACETATE |
| 58016096256 | FLECAINIDE ACETATE |
| 58016096260 | FLECAINIDE ACETATE |
| 58016096290 | FLECAINIDE ACETATE |
| 60505266000 | FLECAINIDE ACETATE |
| 60505266001 | FLECAINIDE ACETATE |
| 60505266003 | FLECAINIDE ACETATE |
| 60505266005 | FLECAINIDE ACETATE |
| 60505266008 | FLECAINIDE ACETATE |
| 60505266100 | FLECAINIDE ACETATE |
| 60505266101 | FLECAINIDE ACETATE |
| 60505266103 | FLECAINIDE ACETATE |
| 60505266105 | FLECAINIDE ACETATE |
| 60505266108 | FLECAINIDE ACETATE |
| 60505266200 | FLECAINIDE ACETATE |
| 60505266201 | FLECAINIDE ACETATE |
| 60505266203 | FLECAINIDE ACETATE |
| 60505266205 | FLECAINIDE ACETATE |
| 63304079401 | FLECAINIDE ACETATE |
| 63304079501 | FLECAINIDE ACETATE |
| 63304079601 | FLECAINIDE ACETATE |
| 65162064110 | FLECAINIDE ACETATE |
| 65162064111 | FLECAINIDE ACETATE |
| 65162064210 | FLECAINIDE ACETATE |
| 65162064211 | FLECAINIDE ACETATE |
| 65162064310 | FLECAINIDE ACETATE |
| 65162064311 | FLECAINIDE ACETATE |
| 66105015202 | TAMBOCOR           |
| 66105015203 | TAMBOCOR           |
| 66105015206 | TAMBOCOR           |
| 66105015209 | TAMBOCOR           |
| 66105015210 | TAMBOCOR           |
| 68084054011 | FLECAINIDE ACETATE |
| 68084054021 | FLECAINIDE ACETATE |
| 68151146402 | FLECAINIDE ACETATE |
| 99207018050 | TAMBOCOR           |
| 99207018110 | TAMBOCOR           |
| 99207018215 | TAMBOCOR           |

End.

## 5) Dofetilide – Tikosyn

| NDC         | DESCRIPTION |
|-------------|-------------|
| 00069580043 | TIKOSYN     |
| 00069580060 | TIKOSYN     |
| 00069580061 | TIKOSYN     |
| 00069581043 | TIKOSYN     |
| 00069581060 | TIKOSYN     |
| 00069581061 | TIKOSYN     |
| 00069582043 | TIKOSYN     |
| 00069582060 | TIKOSYN     |
| 00069582061 | TIKOSYN     |

End.

## 6) Propafenone – Rythmol, Rythmol SR

| NDC         | DESCRIPTION              |
|-------------|--------------------------|
| 00044502202 | RYTHMOL                  |
| 00044502210 | RYTHMOL                  |
| 00044502302 | RYTHMOL                  |
| 00044502310 | RYTHMOL                  |
| 00044502402 | RYTHMOL                  |
| 00044502410 | RYTHMOL                  |
| 00074162812 | RYTHMOL                  |
| 00074162814 | RYTHMOL                  |
| 00074173212 | RYTHMOL                  |
| 00074173214 | RYTHMOL                  |
| 00074183112 | RYTHMOL                  |
| 00074183114 | RYTHMOL                  |
| 00173078601 | RYTHMOL SR               |
| 00173078801 | RYTHMOL SR               |
| 00173078901 | RYTHMOL SR               |
| 00173079220 | RYTHMOL                  |
| 00173079420 | RYTHMOL                  |
| 00173082318 | RYTHMOL SR               |
| 00173082418 | RYTHMOL SR               |
| 00173082618 | RYTHMOL SR               |
| 00591058201 | PROPAFENONE HCL          |
| 00591058301 | PROPAFENONE HCL          |
| 00603544810 | PROPAFENONE, FILM COATED |
| 00603544821 | PROPAFENONE HCL          |
| 00603544825 | PROPAFENONE HCL          |
| 00603544828 | PROPAFENONE, FILM COATED |
| 00603544832 | PROPAFENONE, FILM COATED |
| 00603544910 | PROPAFENONE, FILM COATED |
| 00603544921 | PROPAFENONE HCL          |
| 00603544925 | PROPAFENONE, FILM COATED |
| 00603544928 | PROPAFENONE, FILM COATED |
| 00603544932 | PROPAFENONE, FILM COATED |
| 00603545010 | PROPAFENONE, FILM COATED |
| 00603545021 | PROPAFENONE HCL          |
| 00603545028 | PROPAFENONE, FILM COATED |
| 00603545032 | PROPAFENONE, FILM COATED |
| 00615757439 | PROPAFENONE, FILM COATED |
| 00677181501 | PROPAFENONE HCL          |
| 00677181503 | PROPAFENONE HCL          |
| 00677181505 | PROPAFENONE HCL          |
| 00677181601 | PROPAFENONE HCL          |

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|             |                               |
|-------------|-------------------------------|
| 00677181603 | PROPAFENONE HCL               |
| 00677181605 | PROPAFENONE HCL               |
| 00677181701 | PROPAFENONE HCL               |
| 00677181703 | PROPAFENONE HCL               |
| 00677181705 | PROPAFENONE HCL               |
| 05515509500 | PROPAFENONE, FILM COATED      |
| 21695081460 | PROPAFENONE HCL ER            |
| 49884009901 | PROPAFENONE, EXTENDED RELEASE |
| 49884009902 | PROPAFENONE HCL ER            |
| 49884009905 | PROPAFENONE HCL ER            |
| 49884009909 | PROPAFENONE HCL ER            |
| 49884009910 | PROPAFENONE, EXTENDED RELEASE |
| 49884011301 | PROPAFENONE, EXTENDED RELEASE |
| 49884011302 | PROPAFENONE, EXTENDED RELEASE |
| 49884011305 | PROPAFENONE, EXTENDED RELEASE |
| 49884011309 | PROPAFENONE, EXTENDED RELEASE |
| 49884011310 | PROPAFENONE, EXTENDED RELEASE |
| 49884020902 | PROPAFENONE HCL ER            |
| 49884020905 | PROPAFENONE HCL ER            |
| 49884020909 | PROPAFENONE HCL ER            |
| 49884021001 | PROPAFENONE, EXTENDED RELEASE |
| 49884021002 | PROPAFENONE HCL ER            |
| 49884021005 | PROPAFENONE HCL ER            |
| 49884021009 | PROPAFENONE HCL ER            |
| 49884021010 | PROPAFENONE, EXTENDED RELEASE |
| 49884021101 | PROPAFENONE, EXTENDED RELEASE |
| 49884021102 | PROPAFENONE HCL ER            |
| 49884021105 | PROPAFENONE HCL ER            |
| 49884021109 | PROPAFENONE HCL ER            |
| 49884021110 | PROPAFENONE, EXTENDED RELEASE |
| 50111070801 | PROPAFENONE HCL               |
| 50111070901 | PROPAFENONE HCL               |
| 50111071001 | PROPAFENONE HCL               |
| 51079099601 | PROPAFENONE HCL               |
| 51079099620 | PROPAFENONE HCL               |
| 52544058201 | PROPAFENONE HCL               |
| 52544058301 | PROPAFENONE HCL               |
| 53489055101 | PROPAFENONE HCL               |
| 53489055103 | PROPAFENONE HCL               |
| 53489055105 | PROPAFENONE HCL               |
| 53489055107 | PROPAFENONE, FILM COATED      |
| 53489055110 | PROPAFENONE, FILM COATED      |
| 53489055201 | PROPAFENONE HCL               |
| 53489055203 | PROPAFENONE HCL               |
| 53489055205 | PROPAFENONE HCL               |
| 53489055207 | PROPAFENONE, FILM COATED      |
| 53489055210 | PROPAFENONE, FILM COATED      |
| 53489055301 | PROPAFENONE HCL               |
| 53489055303 | PROPAFENONE HCL               |
| 53489055305 | PROPAFENONE HCL               |
| 53489055307 | PROPAFENONE, FILM COATED      |
| 53489055310 | PROPAFENONE, FILM COATED      |
| 54569613300 | PROPAFENONE HCL               |
| 54868477000 | PROPAFENONE HCL               |
| 54868477001 | PROPAFENONE HYDROCHLORIDE     |
| 54868477002 | PROPAFENONE HYDROCHLORIDE     |
| 54868477003 | PROPAFENONE HCL               |
| 54868477004 | PROPAFENONE HYDROCHLORIDE     |
| 54868477005 | PROPAFENONE HYDROCHLORIDE     |



|             |                           |
|-------------|---------------------------|
| 54868595000 | PROPAFENONE HCL           |
| 54868595001 | PROPAFENONE HCL           |
| 54868595002 | PROPAFENONE, FILM COATED  |
| 58016030300 | PROPAFENONE               |
| 58016030330 | PROPAFENONE               |
| 58016030360 | PROPAFENONE               |
| 58016030390 | PROPAFENONE               |
| 58177033104 | PROPAFENONE HCL           |
| 58177033111 | PROPAFENONE HCL           |
| 58177033112 | PROPAFENONE HCL           |
| 58177033204 | PROPAFENONE HCL           |
| 58177033304 | PROPAFENONE HCL           |
| 62559023001 | PROPAFENONE, FILM COATED  |
| 62559023101 | PROPAFENONE, FILM COATED  |
| 62559023201 | PROPAFENONE, FILM COATED  |
| 63629386901 | PROPAFENONE HCL           |
| 63739050910 | PROPAFENONE, FILM COATED  |
| 63739051010 | PROPAFENONE, FILM COATED  |
| 65726026115 | RYTHMOL SR                |
| 65726026125 | RYTHMOL SR                |
| 65726026190 | RYTHMOL SR                |
| 65726026215 | RYTHMOL SR                |
| 65726026225 | RYTHMOL SR                |
| 65726026290 | RYTHMOL SR                |
| 65726026315 | RYTHMOL SR                |
| 65726026325 | RYTHMOL SR                |
| 65726026390 | RYTHMOL SR                |
| 65726026525 | RYTHMOL                   |
| 65726026590 | RYTHMOL                   |
| 65726026625 | RYTHMOL                   |
| 65726026690 | RYTHMOL                   |
| 65726026725 | RYTHMOL                   |
| 65726026790 | RYTHMOL                   |
| 66993011460 | PROPAFENONE SR            |
| 66993011560 | PROPAFENONE SR            |
| 66993011660 | PROPAFENONE SR            |
| 68084036101 | PROPAFENONE HYDROCHLORIDE |
| 68084036111 | PROPAFENONE HCL           |
| 68084085832 | PROPAFENONE ER            |
| 68084085833 | PROPAFENONE ER            |
| 68084091732 | PROPAFENONE ER            |
| 68084091733 | PROPAFENONE ER            |

End.

## APPENDIX A.2 EXCLUSIONARY CONDITIONS DEFINITIONS – SCREENING CRITERIA APPLIED TO ALL PATIENTS

### History of Cancer

#### ICD-9-CM Diagnosis Range

140 – 209.xx Cancer

V10.x Personal history of malignant neoplasms

### History of Organ Transplant

#### ICD-9-CM Diagnoses

996.81 Complications of a transplanted kidney  
996.82 Complications of a transplanted liver  
996.83 Complications of a transplanted heart  
996.84 Complications of a transplanted lung  
996.86 Complications of a transplanted pancreas  
V42.0x Transplant - Kidney, status post  
V42.1x Transplant – Heart  
V42.6x Transplant – Lung  
V42.7x Transplant - Liver  
V42.83 Pancreas replaced by transplant

#### ICD-9-CM Procedures

33.5 Lung transplant  
33.50 Lung transplantation, not otherwise specified  
33.51 Unilateral lung transplantation  
33.52 Bilateral lung transplantation  
33.6 Combined heart-lung transplantation  
37.51 Heart transplantation  
37.55 Removal of internal biventricular heart replacement system  
52.8 Transplant of pancreas  
52.80 Pancreatic transplant, not otherwise specified  
52.81 Reimplantation of pancreatic tissue  
52.82 Homotransplant of pancreas  
52.83 Heterotransplant of pancreas  
52.84 Autotransplantation of cells of islets of langerhans  
52.85 Allotransplantation of cells of islets of langerhans  
52.86 Transplantation of cells of islets of langerhans, not otherwise specified  
55.53 Removal transplant/rejected kidney  
55.69 Other kidney transplantation

#### CPT® Procedures

32851 Lung transplant, single; without cardiopulmonary bypass  
32852 Lung transplant, single; with cardiopulmonary bypass  
32853 Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass  
32854 Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass  
33935 Heart-lung transplant with recipient cardiectomy-pneumonectomy  
33945 Heart transplant, with or without recipient cardiectomy  
47135 Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age  
47136 Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age  
48160 Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| 48554 | Transplantation of pancreatic allograft                                         |
| 48556 | Removal of transplanted pancreatic allograft                                    |
| 50360 | Renal allotransplantation, implantation of graft; without recipient nephrectomy |
| 50365 | Renal allotransplantation, implantation of graft; with recipient nephrectomy    |
| 50370 | Removal of transplanted renal allograft                                         |
| 50380 | Renal autotransplantation, reimplantation of kidney                             |

## History of HIV

### ICD-9-CM Diagnosis

|     |                                            |
|-----|--------------------------------------------|
| 042 | Human immunodeficiency virus (HIV) disease |
|-----|--------------------------------------------|

## History of Pregnancy (Index date minus 280, through index date minus 1)

### ICD-9-CM Diagnoses

|        |                                                                                                 |
|--------|-------------------------------------------------------------------------------------------------|
| V22    | Normal pregnancy                                                                                |
| V22.0  | Supervision of normal first pregnancy                                                           |
| V22.1  | Supervision of other normal pregnancy                                                           |
| V22.2  | Pregnant state incidental                                                                       |
| V23    | Supervision of high-risk pregnancy                                                              |
| V23.0  | Supervision of high-risk pregnancy with history of infertility                                  |
| V23.1  | Supervision of high-risk pregnancy with history of trophoblastic disease                        |
| V23.2  | Supervision of high-risk pregnancy with history of abortion                                     |
| V23.3  | Supervision of high-risk pregnancy with grand multiparity                                       |
| V23.4  | Supervision of high-risk pregnancy with other poor obstetric history                            |
| V23.41 | Supervision of high-risk pregnancy with history of pre-term labor                               |
| V23.42 | Supervision of high-risk pregnancy with history of ectopic pregnancy                            |
| V23.49 | Supervision of high-risk pregnancy with other poor obstetric history                            |
| V23.5  | Supervision of high-risk pregnancy with other poor reproductive history                         |
| V23.7  | Supervision of high-risk pregnancy with insufficient prenatal care                              |
| V23.8  | Supervision of other high-risk pregnancy                                                        |
| V23.81 | Supervision of high-risk pregnancy with elderly primigravida                                    |
| V23.82 | Supervision of high-risk pregnancy with elderly multigravida                                    |
| V23.83 | Supervision of high-risk pregnancy with young primigravida                                      |
| V23.84 | Supervision of high-risk pregnancy with young multigravida                                      |
| V23.85 | Supervision of high-risk pregnancy resulting from assisted reproductive technology              |
| V23.86 | Supervision of high-risk pregnancy with history of in utero procedure during previous pregnancy |
| V23.87 | Supervision of high-risk pregnancy with inconclusive fetal viability                            |
| V23.89 | Supervision of other high-risk pregnancy                                                        |
| V23.9  | Supervision of unspecified high-risk pregnancy                                                  |
| V28    | Encounter for antenatal screening of mother                                                     |
| V28.0  | Screening for chromosomal anomalies by amniocentesis                                            |
| V28.1  | Screening for raised alpha-fetoprotein levels in amniotic fluid                                 |
| V28.2  | Other antenatal screening based on amniocentesis                                                |
| V28.3  | Encounter for routine screening for malformation using ultrasonics                              |
| V28.4  | Antenatal screening for fetal growth retardation using ultrasonics                              |
| V28.5  | Antenatal screening for isoimmunization                                                         |
| V28.6  | Antenatal screening for streptococcus b                                                         |
| V28.8  | Other specified antenatal screening                                                             |
| V28.81 | Encounter for fetal anatomic survey                                                             |
| V28.82 | Encounter for screening for risk of preterm labor                                               |
| V28.89 | Other specified antenatal screening                                                             |
| V28.9  | Unspecified antenatal screening                                                                 |

### ICD-9-CM Procedures

|       |                                       |
|-------|---------------------------------------|
| 72    | Forceps, vacuum, and breech delivery  |
| 72.0  | Low forceps operation                 |
| 72.1  | Low forceps operation with episiotomy |
| 72.2  | Mid forceps operation                 |
| 72.21 | Mid forceps operation with episiotomy |
| 72.29 | Other mid forceps operation           |

- 72.3 High forceps operation
- 72.31 High forceps operation with episiotomy
- 72.39 Other high forceps operation
- 72.4 Forceps rotation of fetal head
- 72.5 Breech extraction
- 72.51 Partial breech extraction with forceps to aftercoming head
- 72.52 Other partial breech extraction
- 72.53 Total breech extraction with forceps to aftercoming head
- 72.54 Other total breech extraction
- 72.6 Forceps application to aftercoming head
- 72.7 Vacuum extraction
- 72.71 Vacuum extraction with episiotomy
- 72.79 Other vacuum extraction
- 72.8 Other specified instrumental delivery
- 72.9 Unspecified instrumental delivery
- 73 Other procedures inducing or assisting delivery
- 73.0 Artificial rupture of membranes
- 73.01 Induction of labor by artificial rupture of membranes
- 73.09 Other artificial rupture of membranes
- 73.1 Other surgical induction of labor
- 73.2 Internal and combined version and extraction
- 73.21 Internal and combined version without extraction
- 73.22 Internal and combined version with extraction
- 73.3 Failed forceps
- 73.4 Medical induction of labor
- 73.5 Manually assisted delivery
- 73.51 Manual rotation of fetal head
- 73.59 Other manually assisted delivery
- 73.6 Episiotomy
- 73.8 Operations on fetus to facilitate delivery
- 73.9 Other operations assisting delivery
- 73.91 External version assisting delivery
- 73.92 Replacement of prolapsed umbilical cord
- 73.93 Incision of cervix to assist delivery
- 73.94 Pubiotomy to assist delivery
- 73.99 Other operations assisting delivery
- 74 Cesarean section and removal of fetus
- 74.0 Classical cesarean section
- 74.1 Low cervical cesarean section
- 74.2 Extraperitoneal cesarean section
- 74.3 Removal of extratubal ectopic pregnancy
- 74.4 Cesarean section of other specified type
- 74.9 Cesarean section of unspecified type
- 74.91 Hysterotomy to terminate pregnancy
- 74.99 Other cesarean section of unspecified type
- 75 Other obstetric operations
- 75.0 Intra-amniotic injection for abortion
- 75.1 Diagnostic amniocentesis
- 75.2 Intrauterine transfusion
- 75.3 Other intrauterine operations on fetus and amnion
- 75.31 Amnioscopy
- 75.32 Fetal ekg (scalp)
- 75.33 Fetal blood sampling and biopsy
- 75.34 Other fetal monitoring
- 75.35 Other diagnostic procedures on fetus and amnion
- 75.36 Correction of fetal defect
- 75.37 Amnioinfusion
- 75.38 Fetal pulse oximetry

#### **CPT Procedures**

- 59120 Tx ectopic pregnancy abdominal/vaginal appr
- 59121 Tx ectopic pregnancy w/o salping&/oophorectomy

59130 Tx ectopic pregnancy abdl pregnancy  
 59135 Tx ectopic pregnancy ntrstl req tot hyst  
 59136 Tx ectopic pregnancy ntrstl prtl rescj uter  
 59140 Tx ectopic pregnancy cervical w/evacuation  
 59150 Laps tx ectopic preg w/o salping&oophorectomy  
 59151 Laps tx ectopic preg w/salping&oophorectomy  
 59160 Curettage postpartum  
 59200 Insertion cervical dilator separate procedure  
 59300 Episiotomy/vag rpr oth/thn attending  
 59320 Cerclage cervix pregnancy vaginal  
 59325 Cerclage cervix pregnancy abdominal  
 59350 Hysterorrhaphy ruptured uterus  
 59400 Ob care antepartum vag dlvr & postpartum  
 59409 Vaginal delivery only  
 59410 Vaginal delivery only w/postpartum care  
 59412 External cephalic version w/wo tocolysis  
 59414 Delivery placenta separate procedure  
 59425 Antepartum care only 4-6 visits  
 59426 Antepartum care only 7/> visits  
 59430 Postpartum care only separate procedure  
 59510 Ob antepartum care cesarean dlvr & postpartum  
 59514 Cesarean delivery only  
 59515 Cesarean delivery only w/postpartum care  
 59525 Stot/tot hysterectomy after cesaren delivery  
 59610 Routine ob care vag dlvr & postpartum care vb  
 59612 Vaginal delivery after cesarean delivery  
 59614 Vaginal delivery & postpartum care vbac  
 59618 Routine obstetrical care attempted vbac  
 59620 Cesarean delivery attempted vbac  
 59622 Cesarean dlvr & postpartum care attempted vba  
 59812 Tx incomplete abortion any trimester surgical  
 59820 Tx missed abortion first trimester surgical  
 59821 Tx missed abortion second trimester surgical  
 59830 Tx septic abortion surgical  
 59840 Induced abortion dilation and curettage  
 59841 Induced abortion dilation & evaucation  
 59850 Induced abortion 1/> amniotic injx w/d&c/evacj  
 59851 Induce abort 1/> amniot njxs dlvr fetus d&c  
 59852 Induce abort 1/> amniot njxs dlvr fetus hystotm  
 59855 Induced abort 1/> vag suppositories dlvr fetus  
 59856 Induced abort 1/> vag supp dlvr fetus d&c &/evac  
 59857 Induced abort 1/> vag suppos dlvr fetus hystot  
 59866 Multifetal pregnancy reduction  
 59870 Uterine evacuation & curettage hydatidiform mole  
 59871 Removal cerclage suture under anesthesia  
 59897 Unlisted fetal invasive px w/ultrasound  
 59898 Unlisted laparoscopy px maternity care&delivery  
 59899 Unlisted procedure maternity care & delivery  
 76801 Us pregnant uterus 14 wk transabdl 1/1st gestat  
 76802 Us preg uterus 14 wk transabdl each gestation  
 76805 Us preg uterus after 1st trimest 1/1st gestation  
 76810 Us preg uterus > 1st trimester abdl ea gestatio  
 76811 Us preg uterus w/detail fetal anat 1st gestation  
 76812 Us preg uterus detail fetal anat exam ea gestat  
 76813 Us fetal nuchal translucency 1st gestation  
 76814 Us fetal nuchal translucency ea addl gestation  
 76815 Us pregnant uterus limited 1/> fetuses  
 76816 Us preg uterus real time f/u trnsabdl per fetus  
 76817 Us preg uterus real time w/image dcmtn transvag

## History of Pregnancy

### ICD-9-CM Diagnoses

- 631 – 639.xx Ectopic and molar pregnancy and other pregnancy with abortive outcomes
- 640 – 649.xx Complications mainly related to pregnancy
- 650 – 659.xx Normal delivery, and other indications for care in pregnancy, labor, and delivery
- 660 – 669.xx Complications occurring mainly in the course of labor and delivery
- 670 – 677.xx Complications of the puerperium
- 678 – 679.xx Other maternal and fetal complications

## **APPENDIX B.1 SERIOUS LIVER INJURY/DISEASE OUTCOME EVENT DEFINITION; BASELINE EXCLUSIONARY SCREENING**

### **ICD-9-CM Codes / Descriptions**

#### **History of Serious Liver Injury/Disease**

##### **ICD-9-CM Diagnoses**

277.4 Disorders of bilirubin excretion  
570 Acute and subacute necrosis of liver  
571.5 Cirrhosis of liver without mention of alcohol  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
572.8 Other sequelae of chronic liver disease\*  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test  
V42.7 Liver replaced by transplant

##### **ICD-9-CM Procedures**

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver  
50.91 Percutaneous aspiration of liver

##### **CPT® Procedures**

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

### **History of Viral Hepatitis**

- 070.0 Viral Hepatitis A With Hepatic Coma
  - 070.1 Viral Hepatitis A Without Hepatic Coma
  - 070.2 Viral Hepatitis B With Hepatic Coma
  - 070.20 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified Without Hepatitis Delta
  - 070.21 Viral Hepatitis B With Hepatic Coma Acute Or Unspecified With Hepatitis Delta
  - 070.22 Chronic Viral Hepatitis B With Hepatic Coma Without Hepatitis Delta
  - 070.23 Chronic Viral Hepatitis B With Hepatic Coma With Hepatitis Delta
  - 070.3 Viral Hepatitis B Without Mention Of Hepatic Coma
  - 070.30 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified Without Hepatitis Delta
  - 070.31 Viral Hepatitis B Without Hepatic Coma Acute Or Unspecified With Hepatitis Delta
  - 070.32 Chronic Viral Hepatitis B Without Hepatic Coma Without Hepatitis Delta
  - 070.33 Chronic Viral Hepatitis B Without Hepatic Coma With Hepatitis Delta
  - 070.4 Other Specified Viral Hepatitis With Hepatic Coma
  - 070.41 Acute Hepatitis C With Hepatic Coma
  - 070.42 Hepatitis Delta Without Active Hepatitis B Disease With Hepatic Coma
  - 070.43 Hepatitis E With Hepatic Coma
  - 070.44 Chronic Hepatitis C With Hepatic Coma
  - 070.49 Other Specified Viral Hepatitis With Hepatic Coma
  - 070.5 Other Specified Viral Hepatitis Without Mention Of Hepatic Coma
  - 070.51 Acute Hepatitis C Without Mention Of Hepatic Coma
  - 070.52 Hepatitis Delta Without Active Hepatitis B Disease Or Hepatic Coma
  - 070.53 Hepatitis E Without Hepatic Coma
  - 070.54 Chronic Hepatitis C Without Hepatic Coma
  - 070.59 Other Specified Viral Hepatitis Without Hepatic Coma
  - 070.7 Unspecified Viral Hepatitis C
  - 070.70 Unspecified Viral Hepatitis C Without Hepatic Coma
  - 070.71 Unspecified Viral Hepatitis C With Hepatic Coma
  - V02.61 Carrier Or Suspected Carrier Of Hepatitis B
  - V02.62 Carrier Or Suspected Carrier Of Hepatitis C
- 

### **Non-Specific – Other Related Hepatitis**

- 070.6 Unspecified Viral Hepatitis With Hepatic Coma
- 070.9 Unspecified Viral Hepatitis Without Hepatic Coma
- 072.71 Mumps Hepatitis
- 091.62 Secondary Syphilitic Hepatitis
- 571.4 Chronic Hepatitis
- 571.40 Chronic Hepatitis, Unspecified
- 571.41 Chronic Persistent Hepatitis
- 571.42 Autoimmune Hepatitis
- 571.49 Other Chronic Hepatitis



571.8 Other Chronic Nonalcoholic Liver Disease  
572.0 Abscess of Liver  
V02.6 Carrier Or Suspected Carrier Of Viral Hepatitis  
V02.60 Carrier Or Suspected Carrier Of Viral Hepatitis Unspecified  
V02.69 Carrier Or Suspected Carrier Of Other Viral Hepatitis

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### **History of Hereditary Conditions**

271.0 Glycogenosis (Type 1 glycogen storage disease)  
271.1 Galactosemia  
273.4 Alpha-1-Antitrypsin Deficiency  
275.0 Disorders of Iron Metabolism (Hemochromatosis)  
275.01 Hereditary hemochromatosis  
275.03 Other hemochromatosis  
275.1 Disorders of Copper Metabolism (Wilson's disease)  
759.89 Alagille syndrome

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## **APPENDIX B.2 serious liver injury / disease outcome event definition – GROUP A CODES**

### **Group A ICD-9-CM Codes / Descriptions - usually reflects Liver Injury/Disease**

#### **ICD-9-CM Diagnoses** (may occur in any code position; inpatient setting):

570 Acute and subacute necrosis of liver  
572.2 Hepatic coma  
572.4 Hepatorenal syndrome  
V42.7 Liver replaced by transplant

#### **ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

50.5 Liver transplant  
50.51 Auxiliary liver transplant  
50.59 Other transplant of liver

#### **CPT®** (may occur in any code position; inpatient setting):

47135 Liver allotransplantation; orthotopic, partial or whole  
47136 Liver allotransplantation; heterotopic, partial or whole

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## **APPENDIX B.3 serious liver injury / disease outcome event definition – GROUP B CODES**

### **Group B ICD-9-CM Codes / Descriptions - highly suspicious, suggestive of Liver Injury/Disease**

#### **ICD-9-CM Diagnoses** (diagnosis must be a primary diagnosis; inpatient setting):

277.4 Disorders of bilirubin excretion  
571.5 Cirrhosis of liver without mention of alcohol  
572.8 Other sequelae of chronic liver disease  
573.0 Chronic passive congestion of liver  
573.3 Hepatitis, unspecified  
573.8 Other specified disorders of liver  
573.9 Unspecified disorder of liver  
782.4 Jaundice, unspecified  
794.8 Nonspecific abnormal results of liver function test

#### **ICD-9-CM Procedures** (may occur in any code position; inpatient setting):

50.11 Closed (percutaneous) [needle] biopsy of liver  
50.12 Open biopsy of liver  
50.13 Transjugular liver biopsy  
50.14 Laparoscopic liver biopsy  
50.91 Percutaneous aspiration of liver

#### **CPT®** (may occur in any code position; inpatient setting):

47000 Biopsy of liver, needle; percutaneous  
47001 Biopsy of liver, needle; done at time of other major procedure  
47100 Biopsy of liver, wedge  
78205 Liver imaging (SPECT)  
78206 Liver imaging (SPECT); with vascular flow

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## APPENDIX B.4 LIVER INJURY/DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Codes to identify pre-existing risk factors / confounders for serious liver disease propensity score model.

| ICD-9-CM                                 | Diagnosis Code Description                                                       |
|------------------------------------------|----------------------------------------------------------------------------------|
| <b>History of Alcoholism</b>             |                                                                                  |
| 571.0                                    | Alcoholic Fatty Liver                                                            |
| 571.1                                    | Acute Alcoholic Hepatitis                                                        |
| 571.2                                    | Alcoholic Cirrhosis Of Liver                                                     |
| 571.3                                    | Unspecified Alcoholic Liver Damage                                               |
| <b>History of Biliary Duct Disorders</b> |                                                                                  |
| 574.00                                   | Calculus Of Gblldr W Acute Cholecystitis W/O Ment Obs                            |
| 574.01                                   | Calculus Of Gblldr W Acute Cholecystitis W Obstruction                           |
| 574.10                                   | Calculus Of Gblldr W Other Cholecystitis W/O Ment Obs                            |
| 574.11                                   | Calculus Of Gblldr W Other Cholecystitis W Obstruction                           |
| 574.20                                   | Calculus Of Gblldr W/O Ment Cholecystitis W/O Ment Obs                           |
| 574.21                                   | Calculus Of Gblldr W/O Ment Cholecystitis W Obstruction                          |
| 574.30                                   | Calculus Of Bile Duct W Acute Cholecystitis W/O Ment Obs                         |
| 574.31                                   | Calculus Of Bile Duct W Acute Cholecystitis W Obs                                |
| 574.40                                   | Calculus Of Bile Duct W Other Cholecystitis W/O Ment Obs                         |
| 574.41                                   | Calculus Of Bile Duct W Other Cholecystitis W Obs                                |
| 574.50                                   | Calculus Of Bile Duct W/O Ment Cholecystitis W/O Ment Obs                        |
| 574.51                                   | Calculus Of Bile Duct W/O Ment Cholecystitis W Obs                               |
| 574.60                                   | Calculus Gblldr And Bile Duct W Acute Cholecyst W/O Obs                          |
| 574.61                                   | Calculus Gblldr And Bile Duct W Acute Cholecyst W Obs                            |
| 574.70                                   | Calculus Gblldr And Bile Duct W Oth Cholecyst W/O Obs                            |
| 574.71                                   | Calculus Of Gallbladder And Bile Duct With Other Cholecystitis, With Obstruction |
| 574.80                                   | Calculus Gblldr & Bile Duct W Ac & Chr Cholecyst W/O Obs                         |
| 574.81                                   | Calculus Gblldr & Bile Duct W Ac & Chr Cholecyst W Obs                           |
| 574.90                                   | Calculus Gblldr And Bile Duct W/O Cholecyst W/O Obs                              |
| 574.91                                   | Calculus Gblldr And Bile Duct W/O Cholecyst W Obs                                |
| 575.0                                    | Acute Cholecystitis                                                              |
| 575.10                                   | Cholecystitis, Unspecified                                                       |
| 575.11                                   | Chronic Cholecystitis                                                            |
| 575.12                                   | Acute And Chronic Cholecystitis                                                  |
| 575.2                                    | Obstruction Of Gallbladder                                                       |
| 575.3                                    | Hydrops Of Gallbladder                                                           |
| 575.4                                    | Perforation Of Gallbladder                                                       |
| 575.5                                    | Fistula Of Gallbladder                                                           |
| 575.6                                    | Cholesterosis Of Gallbladder                                                     |
| 575.8                                    | Other Specified Disorders Of Gallbladder                                         |
| 575.9                                    | Unspecified Disorder Of Gallbladder                                              |
| 576.1                                    | Cholangitis                                                                      |

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### History of Congestive Heart Failure

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|        |                                                                |
|--------|----------------------------------------------------------------|
| 428    | Heart Failure                                                  |
| 428.0  | Congestive Heart Failure Unspecified                           |
| 428.1  | Left Heart Failure                                             |
| 428.2  | Systolic Heart Failure                                         |
| 428.20 | Unspecified Systolic Heart Failure                             |
| 428.21 | Acute Systolic Heart Failure                                   |
| 428.22 | Chronic Systolic Heart Failure                                 |
| 428.23 | Acute On Chronic Systolic Heart Failure                        |
| 428.3  | Diastolic Heart Failure                                        |
| 428.30 | Unspecified Diastolic Heart Failure                            |
| 428.31 | Acute Diastolic Heart Failure                                  |
| 428.32 | Chronic Diastolic Heart Failure                                |
| 428.33 | Acute On Chronic Diastolic Heart Failure                       |
| 428.4  | Combined Systolic And Diastolic Heart Failure                  |
| 428.40 | Unspecified Combined Systolic And Diastolic Heart Failure      |
| 428.41 | Acute Combined Systolic And Diastolic Heart Failure            |
| 428.42 | Chronic Combined Systolic And Diastolic Heart Failure          |
| 428.43 | Acute On Chronic Combined Systolic And Diastolic Heart Failure |
| 428.9  | Heart Failure Unspecified                                      |

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### History of Diabetes

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|        |                                                               |
|--------|---------------------------------------------------------------|
| 250.xx | Diabetes Mellitus                                             |
| V18.0  | Family History Of Diabetes Mellitus                           |
| V18.1  | Family History Of Other Endocrine And Metabolic Diseases      |
| V18.11 | Family History Of Multiple Endocrine Neoplasia [Men] Syndrome |
| V18.19 | Family History Of Other Endocrine And Metabolic Diseases      |

**History of Diabetes Medication Proxy** (Medication dispensed prior to index date) [from Facts & Comparisons eAnswers – Antidiabetic Agents, accessed April 6, 2015.]

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acarbose  
albiglutide  
alogliptin  
bromocriptine  
canagliflozin  
chlorpropamide  
dapagliflozin  
dulaglutide  
empagliflozin  
exenatide  
glimepiride  
glipizide  
glyburide ( glibenclamide)  
insulin aspart  
insulin detemir  
insulin glargine (rdna origin)

insulin glulisine  
 insulin isophane ( nph)  
 insulin isophane (nph) /insulin regular  
 insulin lispro  
 insulin regular  
 linagliptin  
 liraglutide  
 metformin hydrochloride  
 miglitol  
 nateglinide  
 pioglitazone  
 pramlintide  
 repaglinide  
 rosiglitazone  
 saxagliptin  
 sitagliptin  
 tolazamide  
 tolbutamide  
 alogliptin/metformin hydrochloride  
 alogliptin/pioglitazone  
 canagliflozin/metformin hydrochloride  
 dapagliflozin/metformin  
 empagliflozin/linagliptin  
 glipizide/metformin hydrochloride  
 glyburide/metformin hydrochloride  
 linagliptin/metformin hydrochloride  
 pioglitazone/glimepiride  
 pioglitazone/metformin hydrochloride  
 repaglinide/metformin hydrochloride  
 rosiglitazone/glimepiride  
 rosiglitazone/metformin hydrochloride  
 saxagliptin/metformin hydrochloride  
 sitagliptin/metformin hydrochloride  
 sitagliptin/simvastatin

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## History of obesity

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|        |                                                 |
|--------|-------------------------------------------------|
| 278    | Overweight, Obesity And Other Hyperalimentation |
| 278.0  | Overweight And Obesity                          |
| 278.00 | Obesity Unspecified                             |
| 278.01 | Morbid Obesity                                  |
| 278.02 | Overweight                                      |
| 278.03 | Obesity Hypoventilation Syndrome                |
| V85.41 | BMI 40.0 – 44.9, adult                          |
| V85.42 | BMI 45.0 – 49.9, adult                          |
| V85.43 | BMI 50.0 – 59.9, adult                          |
| V85.44 | BMI 60.0 – 69.9, adult                          |
| V85.45 | BMI 70 and over, adult                          |

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## **Anti-arrhythmic agents other than the study medications**

### **Therapeutic class # 240404\***

|                                            |                             |
|--------------------------------------------|-----------------------------|
| Bretylum Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylum Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride           | Quinidine Polygalacturonate |
| Disopyramide Phosphate                     | Quinidine Sulfate           |
| Lidocaine Hydrochloride                    | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                   |                             |

\* Systemic use; screen for only the agents listed above.

**Hepatotoxic medications\*[Note: current list refers to DoD data; a combined DoD & HIRD list of medications will be provided.]**

| Generic Name (Alias)                                             | Product Name                                       |
|------------------------------------------------------------------|----------------------------------------------------|
| <b>Study Period: 7/20/2008 to 9/30/2014</b>                      |                                                    |
| <b>Acetaminophen (N-Acetyl-P-Aminophenol; APAP)</b>              | <b>Acetaminophen</b>                               |
|                                                                  | Children's Tylenol                                 |
|                                                                  | Children's Q-PAP                                   |
|                                                                  | Genapap                                            |
|                                                                  | Genebs                                             |
|                                                                  | Mapap                                              |
|                                                                  | Mapap Arthritis Pain                               |
|                                                                  | Pain & Fever                                       |
|                                                                  | Pain Relief                                        |
|                                                                  | Pain Relief Extra Strength                         |
|                                                                  | Pain Reliever                                      |
|                                                                  | Q-PAP                                              |
|                                                                  | Sedapap                                            |
|                                                                  | Tylenol 8 Hour                                     |
|                                                                  | Tylenol Cold                                       |
|                                                                  | Tylenol Extra Strength                             |
|                                                                  | Tylenol                                            |
| <b>Acetaminophen in Combination Products</b>                     |                                                    |
| Acetaminophen/Aspirin/Caffeine/Codeine                           | Acetaminophen/Aspirin/Caffeine/ Codeine            |
| Acetaminophen/Aspirin/Caffeine/Salicylamide                      | Levacet                                            |
| Acetaminophen/Atropine/Caffeine/Ephedrine                        | Acetaminophen/Atropine/Caffeine/Ephedrine          |
| Acetaminophen/Caffeine/Dihydrocodeine Bitartrate                 | Acetaminophen/ Caffeine/ Dihydrocodeine Bitartrate |
|                                                                  | Trezix                                             |
| Acetaminophen/Butalbital                                         | BUPAP                                              |
|                                                                  | Cephadyn                                           |
|                                                                  | Sedapap                                            |
|                                                                  | Phrenilin Forte                                    |
| Acetaminophen/Butalbital/Caffeine                                | Acetaminophen/Butalbital/Caffeine                  |
|                                                                  | Dolgic Plus                                        |
|                                                                  | Esgic                                              |
|                                                                  | Esgic-Plus                                         |
|                                                                  | Fioricet                                           |
|                                                                  | Zebutal                                            |
| Acetaminophen/Butalbital/Codeine Phosphate                       | Acetaminophen/Butalbital/Codeine Phosphate         |
| Acetaminophen/Butalbital/Caffeine/Codeine                        | Acetaminophen/ Butalbital /Caffeine/Codeine        |
|                                                                  | Fioricet with Codeine                              |
| Acetaminophen/Caffeine/ Pyrilamine                               | Midol Maximum Strength Menstrual                   |
| Acetaminophen/Calcium Carbonate                                  | Various                                            |
| Acetaminophen/Codeine Phosphate                                  | Acetaminophen/Codeine Phosphate                    |
|                                                                  | Tylenol with Codeine #3                            |
| Acetaminophen/Dextromethorphan/Diphenhydramine/<br>Phenylephrine | Respa C&C                                          |
|                                                                  | Respa C&C IR                                       |
| Acetaminophen/Dextromethorphan                                   | Various                                            |
| Acetaminophen/Guaifenesin                                        | Various                                            |
| Acetaminophen/ Hydrocodone Bitartrate                            | Acetaminophen/ Hydrocodone Bitartrate              |



|                                                             |                                                |
|-------------------------------------------------------------|------------------------------------------------|
|                                                             | Hycet                                          |
|                                                             | Lorcet                                         |
|                                                             | Lortab                                         |
|                                                             | Norco                                          |
|                                                             | Stagesic                                       |
|                                                             | Vicodin                                        |
|                                                             | Vicodin ES                                     |
|                                                             | Vicodin HP                                     |
|                                                             | Xodol 5-300                                    |
|                                                             | Xodol 10-300                                   |
|                                                             | Zamicet                                        |
|                                                             | Zydone                                         |
| Acetaminophen/Isometheptene Mucate/Caffeine                 | Acetaminophen/Isometheptene Mucate/Caffeine    |
|                                                             | Prodrin                                        |
| Acetaminophen<br>/Isometheptene/Dichloralphenazone          | Acetaminophen/Isometheptene/Dichloralphenazone |
|                                                             | Diacetazone                                    |
|                                                             | Epidrin                                        |
|                                                             | I.D.A.                                         |
|                                                             | Midrin                                         |
|                                                             | Migquin                                        |
|                                                             | Migratine                                      |
|                                                             | Migrazone                                      |
| Acetaminophen/Oxycodone HCL                                 | Acetaminophen/Oxycodone HCL                    |
|                                                             | Endocet                                        |
|                                                             | Magnacet                                       |
|                                                             | Percocet                                       |
|                                                             | Roxicet                                        |
|                                                             | Tylox                                          |
|                                                             | Xolox                                          |
| Acetaminophen/Pentazocine                                   | Acetaminophen/Pentazocine                      |
|                                                             | Talacen                                        |
| Acetaminophen/Pheniramine/Phenylephrine                     | Various                                        |
| Acetaminophen/Doxylamine/Phenylephrine/<br>Dextromethorphan | Various                                        |
| Acetaminophen/Phenylephrine                                 | Various                                        |
| Acetaminophen/Phenyltoloxamine                              | Dologesic                                      |
|                                                             | Flextra-650                                    |
|                                                             | Relagesic                                      |
|                                                             | POLY-650                                       |
|                                                             | RhinoFlex-650                                  |
| Acetaminophen/Phenyltoloxamine/Salicylamide                 | Ed-Flex                                        |
|                                                             | Dolorex                                        |
| Acetaminophen/Propoxyphene HCL                              | Propoxyphene HCL /Acetaminophen                |
| Acetaminophen/Propoxyphene Napsylate                        | Propoxyphene Napsylate/Acetaminophen           |
|                                                             | Balacet 325                                    |
|                                                             | Darvocet A500                                  |
|                                                             | Darvocet-N 100                                 |
|                                                             | Darvocet-N 50                                  |
|                                                             | Propacet                                       |
| Acetaminophen/ Tramadol HCL                                 | Tramadol HCL/Acetaminophen                     |
|                                                             | Ultracet                                       |
| <b>Acitretin</b>                                            | Acitretin                                      |

|                                          |                                    |
|------------------------------------------|------------------------------------|
|                                          | Soriatane                          |
| <b>Allopurinol</b>                       | Allopurinol                        |
|                                          | Aloprim                            |
|                                          | Lopurin                            |
|                                          | Zyloprim                           |
| <b>Amitriptyline</b>                     | Amitriptyline                      |
|                                          | Amitid                             |
|                                          | Amitril                            |
|                                          | Elavil                             |
|                                          | Endep                              |
| Amitriptyline HCL/Chlordiazepoxide       | Amitriptyline HCL/Chlordiazepoxide |
|                                          | Limbitrol                          |
|                                          | Limbitrol DS                       |
| Amitriptyline HCL/Perphenazine           | Amitriptyline HCL/Perphenazine     |
|                                          | Etrafon                            |
|                                          | Etrafon A                          |
|                                          | Etrafon Forte                      |
|                                          | Triavil                            |
| <b>Amoxicillin/Potassium Clavulanate</b> | Amoxicillin-Pot Clavulanate        |
|                                          | Augmentin                          |
|                                          | Augmentin ES 600                   |
|                                          | Augmentin XR                       |
| <b>Asparaginase Erwinia Chrysanthemi</b> | Erwinaze                           |
| <b>Azathioprine</b>                      | Azathioprine                       |
|                                          | Azasan                             |
|                                          | Imuran                             |
| <b>Baclofen</b>                          | Baclofen                           |
|                                          | Gablofen                           |
|                                          | Kemstro                            |
|                                          | Lioresal                           |
| <b>Bosentan</b>                          | Tracleer                           |
| <b>Ciprofloxacin</b>                     | Ciprofloxacin                      |
|                                          | Cipro                              |
|                                          | Cipro XR                           |
|                                          | Proquin XR                         |
| <b>Clindamycin</b>                       | Clindamycin Phosphate              |
|                                          | Clindamycin HCL                    |
|                                          | Clindamycin Palmitate HCl          |
|                                          | Cleocin                            |
| <b>Chlorpromazine HCL</b>                | Chlorpromazine                     |
|                                          | Chlorpromazine Intensol            |
|                                          | Promapar                           |
|                                          | Sonazine                           |
|                                          | Thorazine                          |
| <b>Cyclophosphamide</b>                  | Cyclophosphamide                   |
|                                          | Cytoxan                            |
|                                          | Cytoxan Lyophilized                |
|                                          | Lyophilized Cytoxan                |
|                                          | Neosar                             |
| <b>Cytarabine</b>                        | Cytarabine                         |
|                                          | Cytosar-U                          |
|                                          | Depocyt                            |
| <b>Danazol</b>                           | Danazol                            |

|                                            |                               |
|--------------------------------------------|-------------------------------|
|                                            | Danocrine                     |
| <b>Dantrolene Sodium</b>                   | Dantrium                      |
|                                            | Dantrolene Sodium             |
|                                            | Revonto                       |
|                                            | Ryanodex                      |
| <b>Dapsone</b>                             | Dapsone                       |
| <b>Deferasirox</b>                         | Deferasirox                   |
|                                            | Exjade                        |
|                                            | Jadenu                        |
| <b>Desflurane</b>                          | Suprane                       |
| <b>Diclofenac</b>                          | Zorvolex                      |
| Diclofenac Sodium                          | Diclofenac Sodium             |
|                                            | DSG Pak                       |
|                                            | Dyloject                      |
|                                            | Pennsaid                      |
|                                            | Rexaphenac                    |
|                                            | Solaraze                      |
|                                            | Voltaren                      |
|                                            | Voltaren-XR                   |
| Diclofenac Potassium                       | Cambia                        |
|                                            | Cataflam                      |
|                                            | Diclofenac Potassium          |
|                                            | Zipsor                        |
| Diclofenac Epolamine                       | Flector                       |
| Diclofenac Sodium/Misoprostol              | Arthrotec                     |
|                                            | Diclofenac Sodium/Misoprostol |
| <b>Disulfiram</b>                          | Antabuse                      |
|                                            | Disulfiram                    |
| <b>Eltrombopag Olamine</b>                 | Promacta                      |
| <b>Enflurane</b>                           | Enflurane                     |
|                                            | Ethrane                       |
|                                            | Compound 347                  |
| <b>Erythromycin Estolate</b>               | Erythromycin Estolate         |
|                                            | Ilosone                       |
| Erythromycin Estolate/Sulfisoxazole Acetyl | Ilosone Sulfa                 |
| <b>Felbamate</b>                           | Felbamate                     |
|                                            | Felbatol                      |
| <b>Fenofibrate</b>                         |                               |
| Choline Fenofibrate                        | Fenofibric acid               |
|                                            | Trilipix                      |
| Fenofibrate                                | Fenofibrate                   |
|                                            | Lipidil                       |
|                                            | Fenoglide                     |
|                                            | Lipofen                       |
|                                            | Lofibra                       |
|                                            | Tricor                        |
|                                            | Triglide                      |
| Fenofibrate micronized                     | Antara (micronized)           |
|                                            | Fenofibrate micronized        |
|                                            | Tricor (micronized)           |
| <b>Fluconazole</b>                         | Fluconazole                   |
|                                            | Diflucan                      |
| <b>Flutamide</b>                           | Flutamide                     |

|                                                     |                                           |
|-----------------------------------------------------|-------------------------------------------|
| <b>Fluvastatin</b>                                  | Fluvastatin                               |
| Fluvastatin Sodium                                  | Fluvastatin Sodium                        |
|                                                     | Lescol                                    |
|                                                     | Lescol XL                                 |
| <b>Gemfibrozil</b>                                  | Gemfibrozil                               |
|                                                     | Lopid                                     |
| <b>Halothane</b>                                    | Halothane                                 |
|                                                     | Fluothane                                 |
| <b>Hydralazine HCL</b>                              | Hydralazine                               |
|                                                     | Dralzine                                  |
|                                                     | Apresoline                                |
| Hydralazine/Hydrochlorothiazide                     | Apresazide                                |
|                                                     | Apresoline-Esidrix                        |
|                                                     | Hydra-Zide                                |
|                                                     | Hydralazine/Hydrochlorothiazide           |
| Hydralazine/Isosorbide Dinitrate                    | BiDil                                     |
| Hydralazine/Hydrochlorothiazide/Reserpine           | Cam-Ap-Es                                 |
|                                                     | Hydralazine/Hydrochlorothiazide/Reserpine |
|                                                     | Hydrap-ES                                 |
|                                                     | Hydroserpine plus (r-h-h)                 |
|                                                     | SER-A-GEN                                 |
|                                                     | SER-AP-ES                                 |
|                                                     | Unipres                                   |
| Hydralazine/Reserpine                               | Dralserp                                  |
|                                                     | Serpasil-Apresoline                       |
| <b>Infliximab</b>                                   | Remicade                                  |
| <b>Interferon beta-1a</b>                           | Avonex                                    |
|                                                     | Rebif                                     |
| Peginterferon Beta-1a                               | Plegridy                                  |
| <b>Irinotecan HCL</b>                               | Camptosar                                 |
|                                                     | Irinotecan                                |
|                                                     | Onivyde                                   |
| <b>Isoflurane</b>                                   | Isoflurane                                |
|                                                     | Forane                                    |
|                                                     | Terrell                                   |
| <b>Isoniazid (Isonicotinic acid hydrazide; INH)</b> | Isoniazid                                 |
|                                                     | Dow-Isoniazid                             |
|                                                     | Hyzyd                                     |
|                                                     | INH                                       |
|                                                     | Laniazid                                  |
|                                                     | Nydrazid                                  |
|                                                     | Rimifon                                   |
|                                                     | Stanozide                                 |
| Isoniazid/Rifampin                                  | Rifamate                                  |
|                                                     | Isoniazid/Rifampin                        |
| Isoniazid/Pyrazinamide/Rifampin                     | Rifater                                   |
| <b>Isotretinoin</b>                                 | Absorica                                  |
|                                                     | Accutane                                  |
|                                                     | Amnesteem                                 |
|                                                     | Claravis                                  |
|                                                     | Myorisan                                  |
|                                                     | Sortet                                    |
|                                                     | Zenatane                                  |

|                                                          |                                                          |
|----------------------------------------------------------|----------------------------------------------------------|
| <b>Ketoconazole</b>                                      | Ketoconazole                                             |
| <b>Labetalol HCL</b>                                     | Labetalol HCL                                            |
|                                                          | Normodyne                                                |
|                                                          | Trandate                                                 |
| Labetalol HCL/Hydrochlorothiazide                        | Normozide                                                |
|                                                          | Trandate HCT                                             |
| <b>Lapatinib</b>                                         | Lapatinib                                                |
| Lapatinib Ditosylate                                     | Tykerb                                                   |
| <b>Leflunomide</b>                                       | Leflunomide                                              |
|                                                          | Arava                                                    |
| <b>Mercaptopurine (6-Mercaptopurine; 6-MP)</b>           | Mercaptopurine                                           |
|                                                          | Purinethol                                               |
|                                                          | Purixan                                                  |
| <b>Methyltestosterone</b>                                | Android 10                                               |
|                                                          | Metandren                                                |
|                                                          | Methyltestosterone                                       |
|                                                          | Oreton                                                   |
|                                                          | Oreton Methyl                                            |
|                                                          | Testred                                                  |
|                                                          | Virilon                                                  |
| Methyltestosterone/Esterified Estrogens                  | Covaryx                                                  |
|                                                          | Covaryx HS                                               |
|                                                          | EEMT                                                     |
|                                                          | EEMT HS                                                  |
|                                                          | Esterified Estrogens/Methyltestosterone                  |
|                                                          | Esterified Estrogens/Methyltestosterone DS               |
|                                                          | Esterified Estrogens/Methyltestosterone HS               |
| Conjugated Estrogens/Methyltestosterone                  | Premarin with Methyltestosterone                         |
| Conjugated Estrogen /Methyltestosterone /Methamphetamine | Conjugated Estrogen /Methyltestosterone /Methamphetamine |
| <b>Methotrexate (Amethopterin; MTX)</b>                  | Methotrexate                                             |
|                                                          | Abitrexate                                               |
|                                                          | Folex PFS                                                |
|                                                          | Mexate-AQ Preserved                                      |
|                                                          | Mexate                                                   |
|                                                          | Rheumatrex Dose Pack                                     |
|                                                          | Otrexup                                                  |
|                                                          | Rasuvo                                                   |
|                                                          | Trexall                                                  |
| <b>Methyldopa</b>                                        | Methyldopa                                               |
|                                                          | Aldomet                                                  |
| Methyldopate HCL                                         | Methyldopate                                             |
| Methyldopa/Chlorothiazide                                | Aldoclor                                                 |
|                                                          | Methyldopa/Chlorothiazide                                |
| Methyldopa/Hydrochlorothiazide                           | Aldoril                                                  |
|                                                          | Methyldopa/Hydrochlorothiazide                           |
| <b>Minocycline</b>                                       | Minocycline                                              |
|                                                          | Arestin                                                  |
|                                                          | Dynacin                                                  |
|                                                          | Minocin                                                  |
|                                                          | Solodyn                                                  |
|                                                          | Ximino                                                   |
| <b>Natalizumab</b>                                       | Tysabri                                                  |

|                                            |                                            |
|--------------------------------------------|--------------------------------------------|
| <b>Nitrofurantoin</b>                      | Furadantin                                 |
|                                            | Furalan                                    |
|                                            | Nitrofurantoin                             |
| Nitrofurantoin Sodium                      | Ivadantin                                  |
| Nitrofurantoin Macrocrystal                | Nitrofurantoin Macrocrystal                |
|                                            | Macrochantin                               |
| Nitrofurantoin Monohydrate/Macrocrystals   | Nitrofurantoin Monohydrate/Macrocrystals   |
|                                            | Macrobid                                   |
| <b>Oxandrolone</b>                         | Oxandrolone                                |
|                                            | Oxandrin                                   |
| <b>Oxymetholone</b>                        | Anadrol-50                                 |
| <b>Pazopanib HCL</b>                       | Votrient                                   |
| <b>Phenytoin</b>                           | Phenytoin                                  |
|                                            | Dilantin                                   |
| Phenytoin Sodium                           | Phenytoin Sodium                           |
|                                            | Dilantin                                   |
|                                            | Phenytek                                   |
|                                            | Phenytex                                   |
| Phenytoin Sodium Prompt                    | Diphenylan Sodium                          |
| Fosphenytoin Sodium                        | Fosphenytoin Sodium                        |
|                                            | Cerebyx                                    |
| Mephenytoin Sodium                         | Mesantoin                                  |
| <b>Propylthiouracil (PTU)</b>              | Propylthiouracil                           |
| <b>Sulindac</b>                            | Sulindac                                   |
|                                            | Clinoril                                   |
| <b>Telithromycin</b>                       | Ketek                                      |
| <b>Testosterone</b>                        | Androderm                                  |
|                                            | Androgel                                   |
|                                            | Axiron                                     |
|                                            | Fortesta                                   |
|                                            | Natesto                                    |
|                                            | Striant                                    |
|                                            | Testoderm                                  |
|                                            | Testim                                     |
|                                            | Testoderm TTS                              |
|                                            | Testopel                                   |
|                                            | Testosterone                               |
| Testosterone Cypionate                     | Depo-Testosterone                          |
|                                            | Testosterone Cypionate                     |
| Testosterone Enanthate                     | Delatestryl                                |
|                                            | Testosterone Enanthate                     |
|                                            | Testosterone Propionate                    |
| Testosterone undecanoate                   | Aveed                                      |
| Testosterone Cypionate/Estradiol Cypionate | Depo-Testadiol                             |
|                                            | Testosterone Cypionate/Estradiol Cypionate |
| Testosterone Enanthate/Estradiol Valerate  | Ditate-ds                                  |
|                                            | Testosterone Enanthate/Estradiol Valerate  |
| <b>Thioridazine HCL</b>                    | Mellaril                                   |
|                                            | Thioridazine                               |
|                                            | Thioridazine Intensol                      |
| <b>Tolcapone</b>                           | Tasmar                                     |
|                                            | Tolcapone                                  |
| <b>Valproate</b>                           |                                            |

|                    |                    |
|--------------------|--------------------|
| Divalproex Sodium  | Divalproex Sodium  |
|                    | Depakote           |
|                    | Depakote ER        |
|                    | Depakote Sprinkles |
| Valproic Acid      | Valproic Acid      |
|                    | Depakene           |
|                    | Stavzor            |
| Valproate Sodium   | Valproate Sodium   |
|                    | Depacon            |
|                    | Depakene           |
| <b>Zafirlukast</b> | Accolate           |
|                    | Zafirlukast        |
| <b>Zileuton</b>    | Zyflo              |
|                    | Zyflo CR           |

\* Systemic use only.

#### References

Pandit A, Sachdeva T, Bafna P. Drug-Induced Hepatotoxicity: A Review. *J Applied Pharma Science* 02 (05); 2012:233-243.

Mehta N, Ozick LA, Gbadehan E. Drug-Induced Hepatotoxicity. Medscape 2014.

<http://emedicine.medscape.com/article/169814-overview#a1> Accessed September 20, 2015.

## APPENDIX C.1 INTERSTITIAL LUNG DISEASE OUTCOME EVENT – POPULATION 1 (NARROW ILD DEFINITION) BASELINE EXCLUSIONARY SCREENING

### ICD-9-CM Code Descriptions

#### History of Interstitial Lung Disease (Narrow)

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

#### History of Pneumonia

|        |                                                                |
|--------|----------------------------------------------------------------|
| 480    | Viral Pneumonia                                                |
| 480.0  | Pneumonia Due To Adenovirus                                    |
| 480.1  | Pneumonia Due To Respiratory Syncytial Virus                   |
| 480.2  | Pneumonia Due To Parainfluenza Virus                           |
| 480.3  | Pneumonia Due To Sars-Associated Coronavirus                   |
| 480.8  | Pneumonia Due To Other Virus Not Elsewhere Classified          |
| 480.9  | Viral Pneumonia Unspecified                                    |
| 481    | Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia]    |
| 482    | Other Bacterial Pneumonia                                      |
| 482.0  | Pneumonia Due To Klebsiella Pneumoniae                         |
| 482.1  | Pneumonia Due To Pseudomonas                                   |
| 482.2  | Pneumonia Due To Hemophilus Influenzae (H. Influenzae)         |
| 482.3  | Pneumonia Due To Streptococcus                                 |
| 482.30 | Pneumonia Due To Streptococcus Unspecified                     |
| 482.31 | Pneumonia Due To Streptococcus Group A                         |
| 482.32 | Pneumonia Due To Streptococcus Group B                         |
| 482.39 | Pneumonia Due To Other Streptococcus                           |
| 482.4  | Pneumonia Due To Staphylococcus                                |
| 482.40 | Pneumonia Due To Staphylococcus Unspecified                    |
| 482.41 | Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus |
| 482.42 | Methicillin Resistant Pneumonia Due To Staphylococcus Aureus   |
| 482.49 | Other Staphylococcus Pneumonia                                 |
| 482.8  | Pneumonia Due To Other Specified Bacteria                      |
| 482.81 | Pneumonia Due To Anaerobes                                     |
| 482.82 | Pneumonia Due To Escherichia Coli [E.Coli]                     |



|        |                                                  |
|--------|--------------------------------------------------|
| 482.83 | Pneumonia Due To Other Gram-Negative Bacteria    |
| 482.84 | Pneumonia Due To Legionnaires' Disease           |
| 482.89 | Pneumonia Due To Other Specified Bacteria        |
| 482.9  | Bacterial Pneumonia Unspecified                  |
| 483.8  | Pneumonia Due To Other Specified Organism        |
| 485    | Bronchopneumonia Organism Unspecified            |
| 486    | Pneumonia Organism Unspecified                   |
| 487.0  | Influenza with Pneumonia                         |
| 507.0  | Pneumonitis due to inhalation of food or vomitus |
| V12.61 | Personal History of Pneumonia (Recurrent)        |

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### **History of Sarcoidosis**

|     |             |
|-----|-------------|
| 135 | Sarcoidosis |
|-----|-------------|

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## APPENDIX C.2 INTERSTITIAL LUNG DISEASE OUTCOME EVENT NARROW DEFINITION

ICD-9-CM Diagnosis Codes (code must appear as a facility discharge diagnosis):

### ICD-9-CM Code Descriptions

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |

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## APPENDIX D.1 INTERSTITIAL LUNG DISEASE OUTCOME EVENT – POPULATION 2 (BROAD ILD DEFINITION) BASELINE EXCLUSIONARY SCREENING

### ICD-9-CM Code Descriptions

#### **History of Interstitial Lung Disease (Broad)**

|        |                                                                                     |
|--------|-------------------------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                                     |
| 515    | Post-inflammatory pulmonary fibrosis                                                |
| 516.3  | Idiopathic fibrosing alveolitis                                                     |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP)                    |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                                                 |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)                             |
| 516.33 | Acute interstitial pneumonitis (AIP)                                                |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)                        |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                                    |
| 516.36 | Cryptogenic organizing pneumonia (COP)                                              |
| 516.37 | Desquamative interstitial pneumonia (DIP)                                           |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies                        |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy                              |
| 518    | Other diseases of lung                                                              |
| 518.0  | Pulmonary collapse                                                                  |
| 518.1  | Interstitial emphysema                                                              |
| 518.2  | Compensatory emphysema                                                              |
| 518.3  | Pulmonary eosinophilia                                                              |
| 518.4  | Acute edema of lung unspecified                                                     |
| 518.5  | Pulmonary insufficiency following trauma and surgery                                |
| 518.51 | Acute respiratory failure following trauma and surgery                              |
| 518.52 | Other pulmonary insufficiency not elsewhere classified following trauma and surgery |
| 518.53 | Acute and chronic respiratory failure following trauma and surgery                  |
| 518.6  | Allergic bronchopulmonary aspergilliosis                                            |
| 518.7  | Transfusion related acute lung injury (trali)                                       |
| 518.8  | Other diseases of lung                                                              |
| 518.81 | Acute respiratory failure                                                           |
| 518.82 | Other pulmonary insufficiency not elsewhere classified                              |
| 518.83 | Chronic respiratory failure                                                         |
| 518.84 | Acute and chronic respiratory failure                                               |
| 518.89 | Other diseases of lung not elsewhere classified                                     |

### **History of Pneumonia**

|        |                                                                |
|--------|----------------------------------------------------------------|
| 480    | Viral Pneumonia                                                |
| 480.0  | Pneumonia Due To Adenovirus                                    |
| 480.1  | Pneumonia Due To Respiratory Syncytial Virus                   |
| 480.2  | Pneumonia Due To Parainfluenza Virus                           |
| 480.3  | Pneumonia Due To Sars-Associated Coronavirus                   |
| 480.8  | Pneumonia Due To Other Virus Not Elsewhere Classified          |
| 480.9  | Viral Pneumonia Unspecified                                    |
| 481    | Pneumococcal Pneumonia [Streptococcus Pneumoniae Pneumonia]    |
| 482    | Other Bacterial Pneumonia                                      |
| 482.0  | Pneumonia Due To Klebsiella Pneumoniae                         |
| 482.1  | Pneumonia Due To Pseudomonas                                   |
| 482.2  | Pneumonia Due To Hemophilus Influenzae (H. Influenzae)         |
| 482.3  | Pneumonia Due To Streptococcus                                 |
| 482.30 | Pneumonia Due To Streptococcus Unspecified                     |
| 482.31 | Pneumonia Due To Streptococcus Group A                         |
| 482.32 | Pneumonia Due To Streptococcus Group B                         |
| 482.39 | Pneumonia Due To Other Streptococcus                           |
| 482.4  | Pneumonia Due To Staphylococcus                                |
| 482.40 | Pneumonia Due To Staphylococcus Unspecified                    |
| 482.41 | Methicillin Susceptible Pneumonia Due To Staphylococcus Aureus |
| 482.42 | Methicillin Resistant Pneumonia Due To Staphylococcus Aureus   |
| 482.49 | Other Staphylococcus Pneumonia                                 |
| 482.8  | Pneumonia Due To Other Specified Bacteria                      |
| 482.81 | Pneumonia Due To Anaerobes                                     |
| 482.82 | Pneumonia Due To Escherichia Coli [E.Coli]                     |
| 482.83 | Pneumonia Due To Other Gram-Negative Bacteria                  |
| 482.84 | Pneumonia Due To Legionnaires' Disease                         |
| 482.89 | Pneumonia Due To Other Specified Bacteria                      |
| 482.9  | Bacterial Pneumonia Unspecified                                |
| 483.8  | Pneumonia Due To Other Specified Organism                      |
| 485    | Bronchopneumonia Organism Unspecified                          |
| 486    | Pneumonia Organism Unspecified                                 |
| 487.0  | Influenza with Pneumonia                                       |
| 507.0  | Pneumonitis due to inhalation of food or vomitus               |
| V12.61 | Personal History of Pneumonia (Recurrent)                      |

### **History of Sarcoidosis**

|     |             |
|-----|-------------|
| 135 | Sarcoidosis |
|-----|-------------|

## APPENDIX D.2 INTERSTITIAL LUNG DISEASE OUTCOME EVENT BROAD DEFINITION

ICD-9-CM Diagnosis Codes (code must appear as a facility discharge diagnosis):

### ICD-9-CM Code Description

|        |                                                                  |
|--------|------------------------------------------------------------------|
| 495.9  | Unspecified allergic alveolitis and pneumonitis                  |
| 515    | Post-inflammatory pulmonary fibrosis                             |
| 516.3  | Idiopathic fibrosing alveolitis                                  |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified (IIP) |
| 516.31 | Idiopathic pulmonary fibrosis (IPF)                              |
| 516.32 | Idiopathic non-specific interstitial pneumonitis (NSIP)          |
| 516.33 | Acute interstitial pneumonitis (AIP)                             |
| 516.34 | Respiratory bronchiolitis interstitial lung disease (RB-ILD)     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia (LIP)                 |
| 516.36 | Cryptogenic organizing pneumonia (COP)                           |
| 516.37 | Desquamative interstitial pneumonia (DIP)                        |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy           |
| 518.82 | Other pulmonary insufficiency, not elsewhere classified          |

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## APPENDIX E. INTERSTITIAL LUNG DISEASE - RISK FACTORS / CONFOUNDER DEFINITIONS

Codes to identify pre-existing risk factors / confounders for interstitial lung disease propensity score model.

### ICD-9-CM Code Descriptions

#### History of Asthma

|        |                                                      |
|--------|------------------------------------------------------|
| 493    | Asthma                                               |
| 493.0  | Extrinsic Asthma                                     |
| 493.00 | Extrinsic Asthma Unspecified                         |
| 493.01 | Extrinsic Asthma With Status Asthmaticus             |
| 493.02 | Extrinsic Asthma With (Acute) Exacerbation           |
| 493.1  | Intrinsic Asthma                                     |
| 493.10 | Intrinsic Asthma Unspecified                         |
| 493.11 | Intrinsic Asthma With Status Asthmaticus             |
| 493.12 | Intrinsic Asthma With (Acute) Exacerbation           |
| 493.2  | Chronic Obstructive Asthma                           |
| 493.20 | Chronic Obstructive Asthma Unspecified               |
| 493.21 | Chronic Obstructive Asthma With Status Asthmaticus   |
| 493.22 | Chronic Obstructive Asthma With (Acute) Exacerbation |
| 493.8  | Other Specified Asthma                               |
| 493.81 | Exercise-Induced Bronchospasm                        |
| 493.82 | Cough Variant Asthma                                 |
| 493.9  | Asthma Unspecified                                   |
| 493.90 | Asthma Unspecified                                   |
| 493.91 | Asthma Unspecified Type With Status Asthmaticus      |
| 493.92 | Asthma Unspecified With (Acute) Exacerbation         |

#### History of Bronchitis

|        |                                                          |
|--------|----------------------------------------------------------|
| 490    | Bronchitis Not Specified As Acute Or Chronic             |
| 491    | Chronic Bronchitis                                       |
| 491.0  | Simple Chronic Bronchitis                                |
| 491.1  | Mucopurulent Chronic Bronchitis                          |
| 491.2  | Obstructive Chronic Bronchitis                           |
| 491.20 | Obstructive Chronic Bronchitis Without Exacerbation      |
| 491.21 | Obstructive Chronic Bronchitis With (Acute) Exacerbation |
| 491.22 | Obstructive Chronic Bronchitis With Acute Bronchitis     |
| 491.8  | Other Chronic Bronchitis                                 |
| 491.9  | Unspecified Chronic Bronchitis                           |
| 494    | Bronchiectasis                                           |
| 494.0  | Bronchiectasis Without Acute Exacerbation                |
| 494.1  | Bronchiectasis With Acute Exacerbation                   |

**History of chronic obstructive pulmonary disease**

|     |                                                     |
|-----|-----------------------------------------------------|
| 496 | Chronic Airway Obstruction Not Elsewhere Classified |
|-----|-----------------------------------------------------|

**History of connective tissue disease**

|        |                                            |
|--------|--------------------------------------------|
| 136.1  | Behçet syndrome (very rare)                |
| 446.21 | Goodpasture syndrome                       |
| 710.0  | Systemic lupus erythematosus               |
| 710.1  | Systemic sclerosis                         |
| 710.2  | Sjögren syndrome                           |
| 710.3  | Dermatomyositis                            |
| 710.4  | Polymyositis                               |
| 710.8  | Mixed connective tissue disease            |
| 710.9  | Undifferentiated connective tissue disease |
| 714.xx | Rheumatoid arthritis                       |
| 720.0  | Ankylosing spondylitis (rare)              |

**History of exposure to occupational and environmental toxins**

|       |                                                                     |
|-------|---------------------------------------------------------------------|
| 495   | Extrinsic Allergic Alveolitis                                       |
| 495.0 | Farmers' Lung                                                       |
| 495.1 | Bagassosis                                                          |
| 495.2 | Bird-Fanciers' Lung                                                 |
| 495.3 | Suberosis                                                           |
| 495.4 | Malt Workers' Lung                                                  |
| 495.5 | Mushroom Workers' Lung                                              |
| 495.6 | Maple Bark-Strippers' Lung                                          |
| 495.7 | Ventilation Pneumonitis                                             |
| 495.8 | Other Specified Allergic Alveolitis And Pneumonitis                 |
| 495.9 | Unspecified Allergic Alveolitis And Pneumonitis                     |
| 500   | Coal Workers' Pneumoconiosis                                        |
| 501   | Asbestosis                                                          |
| 502   | Pneumoconiosis Due To Other Silica Or Silicates                     |
| 503   | Pneumoconiosis Due To Other Inorganic Dust                          |
| 504   | Pneumonopathy Due To Inhalation Of Other Dust                       |
| 505   | Pneumoconiosis Unspecified                                          |
| 506   | Respiratory Conditions Due To Chemical Fumes And Vapors             |
| 506.0 | Bronchitis And Pneumonitis Due To Fumes And Vapors                  |
| 506.1 | Acute Pulmonary Edema Due To Fumes And Vapors                       |
| 506.2 | Upper Respiratory Inflammation Due To Fumes And Vapors              |
| 506.3 | Other Acute And Subacute Resp Conditions Due To Fumes And Vapors    |
| 506.4 | Chronic Respiratory Conditions Due To Fumes And Vapors              |
| 506.9 | Unspecified Respiratory Conditions Due To Fumes And Vapors          |
| 507   | Pneumonitis Due To Solids And Liquids                               |
| 507.1 | Pneumonitis Due To Inhalation Of Oils And Essences                  |
| 507.8 | Pneumonitis Due To Other Solids And Liquids                         |
| 508   | Respiratory Conditions Due To Other And Unspecified External Agents |

|       |                                                               |
|-------|---------------------------------------------------------------|
| 508.0 | Acute Pulmonary Manifestations Due To Radiation               |
| 508.1 | Chronic And Other Pulmonary Manifestations Due To Radiation   |
| 508.2 | Respiratory Conditions Due To Smoke Inhalation                |
| 508.8 | Respiratory Conditions Due To Other Specified External Agents |
| 508.9 | Respiratory Conditions Due To Unspecified External Agent      |

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#### **History of gastroesophageal reflux disease**

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|        |                                 |
|--------|---------------------------------|
| 530.81 | Gastroesophageal reflux disease |
|--------|---------------------------------|

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#### **Anti-arrhythmic agents other than the study medications**

##### **Therapeutic class # 240404\***

|                                             |                             |
|---------------------------------------------|-----------------------------|
| Bretylium Tosylate (Discontinued June 2011) | Procainamide Hydrochloride  |
| Bretylium Tosylate/Dextrose                 | Quinidine Gluconate         |
| Dextrose/Lidocaine Hydrochloride            | Quinidine Polygalacturonate |
| Disopyramide Phosphate                      | Quinidine Sulfate           |
| Lidocaine Hydrochloride                     | Tocainide Hydrochloride     |
| Mexiletine Hydrochloride                    |                             |

\* Systemic use; screen for only the agents listed above.

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## **History of therapeutic oxygen treatment**

### **Oxygen Therapy – CPT Procedure Codes**

| <b>CPT</b> | <b>CPT Description</b>                                                                                                                                                                                                                                                                          |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4030F      | Long-term oxygen therapy prescribed (more than 15 hours per day) (COPD)                                                                                                                                                                                                                         |
| 82803      | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub>                                                                                                                                                                                    |
| 82805      | Gases, blood, any combination of pH, pCO <sub>2</sub> , pO <sub>2</sub> , CO <sub>2</sub> , HCO <sub>3</sub> (including calculated O <sub>2</sub> saturation); with O <sub>2</sub> saturation, by direct measurement, except pulse oximetry                                                     |
| 82810      | Gases, blood, O <sub>2</sub> saturation only, by direct measurement, except pulse oximetry                                                                                                                                                                                                      |
| 94010      | Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation                                                                                                                                        |
| 94014      | Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and review and interpretation by a physician/other qualified health care professional |
| 94015      | Patient-initiated spirometric recording per 30-day period of time; recording                                                                                                                                                                                                                    |
| 94016      | Patient-initiated spirometric recording per 30-day period of time; review and interpretation only by a physician or other qualified health care professional                                                                                                                                    |
| 94060      | Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator admin                                                                                                                                                                                                      |
| 94070      | Bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (eg, antigen[s], cold air, methacholine)                                                                                                                                         |
| 94150      | Vital capacity, total (separate procedure)                                                                                                                                                                                                                                                      |
| 94200      | Maximum breathing capacity, maximal voluntary ventilation                                                                                                                                                                                                                                       |
| 94250      | Expired gas collection, quantitative, single procedure (separate procedure)                                                                                                                                                                                                                     |
| 94375      | Respiratory flow volume loop                                                                                                                                                                                                                                                                    |
| 94400      | Breathing response to CO <sub>2</sub> (CO <sub>2</sub> response curve)                                                                                                                                                                                                                          |
| 94450      | Breathing response to hypoxia (hypoxia response curve)                                                                                                                                                                                                                                          |



|       |                                                                                                                                                                     |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 94452 | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional;                                    |
| 94453 | High altitude simulation test (HAST), with interpretation and report by a physician or other qualified health care professional; with supplemental oxygen titration |
| 94610 | Intrapulmonary surfactant administration by a physician or other qualified health care professional through endotracheal tube                                       |
| 94620 | Pulmonary stress testing; simple                                                                                                                                    |
| 94621 | Pulmonary stress testing; complex                                                                                                                                   |
| 94640 | Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes                                     |
| 94642 | Aerosol inhalation of pentamidine for pneumocystis carinii pneumonia treatment/prophylaxis                                                                          |
| 94644 | Continuous inhalation treatment w aerosol medication for acute airway obstruction; 1 <sup>st</sup> hour                                                             |
| 94645 | Continuous inhalation treatment w/ aerosol medication for acute airway obstruction; ea add hr                                                                       |
| 94660 | Continuous positive airway pressure ventilation (CPAP), initiation and management                                                                                   |
| 94662 | Continuous negative pressure ventilation (CNP), initiation and management                                                                                           |
| 94664 | Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device                                      |
| 94667 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation                            |
| 94668 | Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent                                                         |
| 94680 | Oxygen uptake, expired gas analysis; rest and exercise, direct, simple                                                                                              |
| 94681 | Oxygen uptake, expired gas analysis; including CO2 output, percentage oxygen extracted                                                                              |
| 94690 | Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)                                                                                            |
| 94726 | Plethysmography for determination of lung volumes and, when performed, airway resistance                                                                            |
| 94727 | Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes                                      |
| 94728 | Airway resistance by impulse oscillometry                                                                                                                           |
| 94729 | Diffusing capacity (eg, carbon monoxide, membrane)                                                                                                                  |
| 94750 | Pulmonary compliance study (eg, plethysmography, volume and pressure measurements)                                                                                  |
| 94760 | Noninvasive ear or pulse oximetry for oxygen saturation; single determination                                                                                       |
| 94761 | Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations                                                                                    |
| 94762 | Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring                                                                         |
| 94770 | Carbon dioxide, expired gas determination by infrared analyzer                                                                                                      |
| 99503 | Home visit - respiratory therapy care (eg, oxygen therapy, respiratory assessment, apnea eval)                                                                      |
| 99504 | Home visit for mechanical ventilation care                                                                                                                          |

### **Oxygen Therapy – HCPCS Procedure Codes**

| <b>HCPCS</b> | <b>HCPCS Description</b>                                                                                                                                                                  |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E0424        | Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                               |
| E0425        | Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                                             |
| E0430        | Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing                                                                          |
| E0431        | Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing                                                        |
| E0433        | Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and |

tubing, with or without supply reservoir and content gauge

|       |                                                                                                                                                                                             |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E0434 | Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing                    |
| E0435 | Portable liquid oxygen system purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor                    |
| E0439 | Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                                             |
| E0440 | Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing                          |
| E0441 | Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit                         |
| E0442 | Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit                            |
| E0443 | Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                   |
| E0444 | Portable oxygen contents, liquid (for use only with portable liquid systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit                                     |
| E1390 | Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate                                                     |
| E1391 | Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each                                                 |
| E1392 | Portable oxygen concentrator, rental                                                                                                                                                        |
| E1405 | Oxygen and water vapor enriching system with heated delivery                                                                                                                                |
| E1406 | Oxygen and water vapor enriching system without heated delivery                                                                                                                             |
| K0738 | Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing |
| K0741 | Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches                                   |
| S8120 | Oxygen contents, gaseous, 1 unit equals 1 cubic foot                                                                                                                                        |
| S8121 | Oxygen contents, liquid, 1 unit equals 1 pound                                                                                                                                              |

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## Agents Associated with Drug-Induced Pulmonary Disease\*

| Generic Name (Alias)<br>Study Period: 7/20/2008 to 9/30/2014 | Product Name                                                                                |
|--------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| <b>Low Risk Categories</b>                                   |                                                                                             |
| <b>Antimicrobial Medications</b>                             |                                                                                             |
| Ethambutol HCL                                               | Ethambutol HCL<br>Myambutol                                                                 |
| Isoniazid (Isonicotinic acid hydrazide; INH)                 | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid<br>Nydrazid<br>Rimifon<br>Stanozide  |
| Isoniazid/Rifampin                                           | Rifamate<br>Isoniazid/Rifampin                                                              |
| Isoniazid/Pyrazinamide/Rifampin                              | Rifater                                                                                     |
| Minocycline                                                  | Minocycline HCL<br>Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                       |
| Sulfasalazine                                                | Sulfasalazine<br>Azulfidine<br>Azulfidine EN-tabs<br>Sulfazine<br>Sulfazine EC<br>S.A.S.500 |
| <b>Cardiovascular Agents</b>                                 |                                                                                             |
| ACE inhibitors                                               |                                                                                             |
| Benazepril HCL                                               | Benazepril HCL<br>Lotensin                                                                  |
| Amlodipine Besylate/Benazepril HCL                           | Amlodipine besylate/Benazepril HCL<br>Lotrel                                                |
| Captopril                                                    | Captopril<br>Capoten                                                                        |
| Enalapril Maleate Oral                                       | Enalapril Maleate<br>Epaned<br>Vasotec                                                      |
| Enalaprilat                                                  | Enalaprilat                                                                                 |
| Enalapril Maleate/Felodipine                                 | Lexxel                                                                                      |
| Enalapril Maleate/Diltiazem Malate                           | Teczem                                                                                      |
| Fosinopril Sodium                                            | Fosinopril Sodium<br>Monopril                                                               |
| Lisinopril                                                   | Lisinopril<br>Prinivil<br>Zestril                                                           |
| Moexipril HCL                                                | Moexipril HCL<br>Univasc                                                                    |
| Perindopril Erbumine                                         | Perindopril Erbumine                                                                        |

|                               |                            |
|-------------------------------|----------------------------|
|                               | Aceon                      |
| Quinapril HCL                 | Quinapril HCL              |
|                               | Accupril                   |
| Ramipril                      | Ramipril                   |
|                               | Altace                     |
| Trandolapril                  | Trandolapril               |
|                               | Mavik                      |
| Trandolapril/Verapamil HCL    | Tarka                      |
|                               | Trandolapril/Verapamil HCL |
| Amiodarone HCL                | Amiodarone HCL             |
|                               | Cordarone                  |
|                               | Nexterone                  |
|                               | Pacerone                   |
| <b>Anticoagulants</b>         |                            |
| Apixaban                      | Eliquis                    |
| Dabigatran Etexilate Mesylate | Pradaxa                    |
| Vorapaxar Sulfate             | Zontivity                  |
| Rivaroxaban                   | Xarelto                    |
|                               | Xarelto Starter Pack       |
| Warfarin Sodium Oral          | Warfarin Sodium            |
|                               | Athrombin                  |
|                               | Athrombin K                |
|                               | Coumadin                   |
|                               | Jantoven                   |
|                               | Panwarfin                  |
| Warfarin Potassium            | Athrombin K                |
| Ticagrelor                    | Brilinta                   |
| <b>Beta Blockers</b>          |                            |
| Acebutolol HCL                | Acebutolol HCL             |
|                               | Sectral                    |
| Atenolol                      | Atenolol                   |
|                               | Tenormin                   |
| Betaxolol HCL                 | Betaxolol HCL              |
|                               | Kerlone                    |
| Bisoprolol Fumarate           | Bisoprolol Fumarate        |
|                               | Zebeta                     |
|                               | Cartrol                    |
| Carteolol HCL                 | Cartrol                    |
| Carvedilol                    | Carvedilol                 |
|                               | Coreg                      |
| Carvedilol Phosphate          | Coreg CR                   |
| Esmolol HCL                   | Esmolol HCL                |
|                               | Brevibloc                  |
| Labetalol HCL                 | Labetalol HCL              |
|                               | Normodyne                  |
|                               | Trandate                   |
| Metoprolol                    |                            |
| Metoprolol Succinate          | Metoprolol Succinate       |
|                               | Toprol XL                  |
| Metoprolol Tartrate           | Metoprolol Tartrate        |
|                               | Lopressor                  |
| Nadolol                       | Nadolol                    |

|                                                                    |                                           |
|--------------------------------------------------------------------|-------------------------------------------|
|                                                                    | Corgard                                   |
| Nebivolol HCL                                                      | Nebivolol HCL                             |
|                                                                    | Bystolic                                  |
| Penbutolol Sulfate                                                 | Levatol                                   |
| Pindolol                                                           | Pindolol                                  |
|                                                                    | Visken                                    |
| Propranolol HCL                                                    | Propranolol HCL                           |
|                                                                    | Hemangeol                                 |
|                                                                    | Inderal LA                                |
|                                                                    | Inderal XL                                |
|                                                                    | InnoPran XL                               |
| Timolol Maleate                                                    | Timolol Maleate                           |
| Flecainide Acetate                                                 | Flecainide Acetate                        |
|                                                                    | Tambocor                                  |
| Hydralazine HCL                                                    | Hydralazine HCL                           |
|                                                                    | Dralzine                                  |
|                                                                    | Apresoline                                |
| Hydralazine/Isosorbide dinitrate                                   | BiDil                                     |
| Hydralazine/Hydrochlorothiazide/Reserpine                          | Cam-Ap-Es                                 |
|                                                                    | Hydralazine/Hydrochlorothiazide/Reserpine |
|                                                                    | Hydrap-ES                                 |
|                                                                    | Hydroserpine plus (r-h-h)                 |
|                                                                    | SER-A-GEN                                 |
|                                                                    | SER-AP-ES                                 |
|                                                                    | Unipres                                   |
| Hydralazine/Reserpine                                              | Dralserp                                  |
|                                                                    | Serpasil-Apresoline                       |
| Hydrochlorothiazide                                                | Esidrix                                   |
|                                                                    | Hydrochlorothiazide                       |
|                                                                    | Hydro-D                                   |
|                                                                    | Hydrodiuril                               |
|                                                                    | Microzide                                 |
|                                                                    | Oretic                                    |
|                                                                    | Zide                                      |
| Spironolactone/Hydrochlorothiazide                                 | Aldactazide                               |
|                                                                    | Spironolactone/Hydrochlorothiazide        |
| Methyldopa/Hydrochlorothiazide                                     | Aldoril                                   |
|                                                                    | Methyldopa/Hydrochlorothiazide            |
| Amiloride HCL/Hydrochlorothiazide                                  | Amiloride HCL/Hydrochlorothiazide         |
|                                                                    | Hydro-ride                                |
|                                                                    | Moduretic                                 |
| Amlodipine/ Valsartan/Hydrochlorothiazide                          | Amlodipine/ Valsartan/Hydrochlorothiazide |
| Aliskiren Hemifumarate/Hydrochlorothiazide                         | Tekturna HCT                              |
| Aliskiren Hemifumarate/Amlodipine Besylate/<br>Hydrochlorothiazide | Amturnide                                 |
| Candesartan Cilexetil/Hydrochlorothiazide                          | Atacand HCT                               |
|                                                                    | Candesartan Cilexetil/Hydrochlorothiazide |
| Irbesartan/Hydrochlorothiazide                                     | Avalide                                   |
|                                                                    | Irbesartan/Hydrochlorothiazide            |
| Olmesartan Medoxomil/Hydrochlorothiazide                           | Benicar HCT                               |
| Valsartan/Hydrochlorothiazide                                      | Diovan HCT                                |
|                                                                    | Valsartan/Hydrochlorothiazide             |
| Triamterene/Hydrochlorothiazide                                    | Dyazide                                   |

|                                                         |                                         |
|---------------------------------------------------------|-----------------------------------------|
| Guanethidine monosulfate/Hydrochlorothiazide            | Maxzide                                 |
| Amlodipine/Valsartan/Hydrochlorothiazide                | Triamterene/Hydrochlorothiazide         |
| Hydrochlorothiazide/Reserpine                           | Esimil                                  |
|                                                         | Exforge HCT                             |
|                                                         | H.R.-50                                 |
|                                                         | Hydro-Reserp                            |
|                                                         | Hydro-serp                              |
|                                                         | Hydropres                               |
| Losartan Potassium/Hydrochlorothiazide                  | Hyzaar                                  |
|                                                         | Losartan Potassium/Hydrochlorothiazide  |
| Telmisartan/Hydrochlorothiazide                         | Micardis HCT                            |
|                                                         | Telmisartan/Hydrochlorothiazide         |
| Deserpidine/Hydrochlorothiazide                         | Oreticyl                                |
|                                                         | Oreticyl Forte                          |
| Eprosartan Mesylate/Hydrochlorothiazide                 | Teveten HCT                             |
| Olmesartan Medoxomil / Amlodipine / Hydrochlorothiazide | Tribenzor                               |
| Procainamide HCL                                        | Procainamide HCL                        |
|                                                         | Procan                                  |
|                                                         | Procan SR                               |
|                                                         | Procanbid                               |
|                                                         | Procapan                                |
|                                                         | Pronestyl                               |
|                                                         | Pronestyl-SR                            |
| Tocainide                                               | Tonocard                                |
| <b>ACE inhibitors/ Hydrochlorothiazide</b>              |                                         |
| Benazepril HCL/Hydrochlorothiazide                      | Benazepril HCL/Hydrochlorothiazide      |
|                                                         | Lotensin HCT                            |
| Captopril/Hydrochlorothiazide                           | Captopril/Hydrochlorothiazide           |
|                                                         | Capozide                                |
| Enalapril Maleate/Hydrochlorothiazide                   | Enalapril Maleate/Hydrochlorothiazide   |
|                                                         | Vaseretic                               |
| Fosinopril Sodium//Hydrochlorothiazide                  | Fosinopril Sodium//Hydrochlorothiazide  |
|                                                         | Monopril HCT                            |
| Lisinopril/Hydrochlorothiazide                          | Lisinopril/Hydrochlorothiazide          |
|                                                         | Prinzide                                |
|                                                         | Zestoretic                              |
| Moexipril HCL/Hydrochlorothiazide                       | Moexipril HCL/Hydrochlorothiazide       |
|                                                         | Uniretic                                |
| Quinapril HCL/Hydrochlorothiazide                       | Quinapril HCL/Hydrochlorothiazide       |
|                                                         | Accuretic                               |
|                                                         | Quinaretic                              |
| <b>Beta Blockers/Thiazide Diuretics</b>                 |                                         |
| Atenolol/Chlorthalidone                                 | Atenolol/Chlorthalidone                 |
|                                                         | Tenoretic 50                            |
| Betaxolol HCL/Chlorthalidone                            | Kerledex                                |
| Bisoprolol Fumarate/Hydrochlorothiazide                 | Bisoprolol Fumarate/Hydrochlorothiazide |
|                                                         | Ziac                                    |
| Labetalol HCL/Hydrochlorothiazide                       | Normozide                               |
|                                                         | Trandate HCT                            |
| Metoprolol Succinate/Hydrochlorothiazide                | Dutoprol                                |
| Metoprolol Tartrate/Chlorthalidone                      | Lopressidone                            |
| Metoprolol Tartrate/Hydrochlorothiazide                 | Metoprolol Tartrate/Hydrochlorothiazide |

|                                     |                                     |
|-------------------------------------|-------------------------------------|
|                                     | Lopressor HCT                       |
| Nadolol/Bendroflumethiazide         | Nadolol/Bendroflumethiazide         |
|                                     | Corzide                             |
| Pindolol/Hydrochlorothiazide        | Viskazine                           |
| Propranolol HCL/Hydrochlorothiazide | Propranolol HCL/Hydrochlorothiazide |
|                                     | Inderide                            |
|                                     | Inderide LA                         |
| Timolol Maleate/Hydrochlorothiazide | Timolide 10-25                      |
| Hydralazine/Hydrochlorothiazide     | Hydra-Zide                          |
|                                     | Apresoline-Esidrix                  |
| <b>Miscellaneous</b>                |                                     |
| Phentermine HCL                     | Adipex-P                            |
|                                     | Fastin                              |
|                                     | Obestin-30                          |
|                                     | Oby-Trim                            |
|                                     | Ona-Mast                            |
|                                     | Phentermine HCL                     |
|                                     | Suprenza                            |
|                                     | Tora                                |
|                                     | Wilpo                               |

## High Risk Categories

### Anti-Inflammatory Medications

|                                  |                      |
|----------------------------------|----------------------|
| Gold                             |                      |
| Gold Sodium Thiomalate           | Myochrysine          |
| Auranofin (29% Gold)             | Ridaura              |
| Methotrexate (Amethepterin; MTX) | Methotrexate         |
|                                  | Abitrexate           |
|                                  | Folex PFS            |
|                                  | Mexate-AQ Preserved  |
|                                  | Mexate               |
|                                  | Rheumatrex Dose Pack |
|                                  | Otrexup              |
|                                  | Rasuvo               |
|                                  | Trexall              |
| Penicillamine                    | Cuprimine            |
|                                  | Depen Titratabs      |

### Monoclonal Antibodies- Antineoplastics

|             |           |
|-------------|-----------|
| Alemtuzumab | Campath   |
|             | Lemtrada  |
| Bevacizumab | Avastin   |
| Cetuximab   | Erbitux   |
| Rituximab   | Rituxan   |
| Trastuzumab | Herceptin |

### Tumor Necrosis Factor-alpha (TNFα) blockers

|                    |                                |
|--------------------|--------------------------------|
| Adalimumab         | Humira                         |
| Certolizumab Pegol | Cimzia (Prefilled/Starter Kit) |
| Etanercept         | Enbrel                         |
| Golimumab          | Simponi                        |
|                    | Simponi Aria                   |
| Infliximab         | Remicade                       |



|                                                     |                                                                                                             |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Immune Globulin Intravenous (Human)                 | Bivigam<br>Carimune NF<br>Flebogamma DIF<br>Gammagard S/D<br>Gammagard S/D Less IgA<br>Gammaplex<br>Octagam |
| <b>Chemotherapeutic Agents</b>                      |                                                                                                             |
| Bicalutamide                                        | Bicalutamide<br>Casodex                                                                                     |
| Bleomycin Sulfate                                   | Bleomycin Sulfate<br>Blenoxane                                                                              |
| Busulfan                                            | Busulfex<br>Myleran                                                                                         |
| Carboplatin                                         | Carboplatin                                                                                                 |
| Capecitabine                                        | Capecitabine<br>Xeloda                                                                                      |
| Carmustine (BCNU)<br>Carmustine in Polifeprosan     | BiCNU<br>Gliadel Wafer                                                                                      |
| Chlorambucil                                        | Leukeran                                                                                                    |
| Cisplatin (CDDP)                                    | Cisplatin<br>Platinol                                                                                       |
| Cyclophosphamide                                    | Cyclophosphamide<br>Cytosan<br>Neosar                                                                       |
| Cytarabine<br>Cytarabine Liposome                   | Cytarabine<br>Cytosar-U<br>DepoCyt                                                                          |
| Doxorubicin HCl                                     | Adriamycin PFS<br>Doxil (Liposomal)<br>Doxorubicin HCL<br>Doxorubicin HCL (liposomal)                       |
| Erlotinib                                           | Erlotinib HCL<br>Tarceva                                                                                    |
| Etoposide<br>Etoposide Phosphate                    | Etoposide<br>Toposar<br>VePesid<br>Etopophos                                                                |
| Floxuridine                                         | Floxuridine<br>FUDR                                                                                         |
| Fludarabine Phosphate                               | Fludara<br>Fludarabine Phosphate<br>Oforta                                                                  |
| Fluorouracil                                        | Adrucil<br>Fluorouracil                                                                                     |
| Flutamide                                           | Flutamide<br>Eulexin                                                                                        |
| Imatinib Mesylate                                   | Gleevec                                                                                                     |
| Interleukin 2<br>Aldesleukin<br>Denileukin diftitox | Proleukin<br>Ontak                                                                                          |
| Lomustine (CCNU)                                    | Lomustine                                                                                                   |

|                                             |                                             |
|---------------------------------------------|---------------------------------------------|
|                                             | Gleostine                                   |
| Melphalan HCL (Phenylalanine mustard)       | Melphalan HCL<br>Alkeran                    |
| Mercaptopurine                              | Mercaptopurine<br>Purinethol<br>Purixan     |
| Semustin                                    | Methyl-CCNU                                 |
| Mitomycin (Mitomycin-C; MTC)                | Mitomycin<br>Mitozytrex<br>Mutamycin        |
| Paclitaxel                                  | Abraxane<br>Paclitaxel<br>Taxol             |
| Procarbazine                                | Matulane                                    |
| Vinblastine Sulfate (VLB)                   | Vinblastine Sulfate                         |
| <b>Interferon Therapy</b>                   |                                             |
| Interferon Alfa -2B                         | Intron A                                    |
| Interferon Alfa- N3                         | Alferon N                                   |
| Interferon Alfacon-1                        | Infergen                                    |
| Interferon Beta-1A                          | Avonex<br>Rebif                             |
| Interferon Beta-1B                          | Betaseron<br>Extavia                        |
| Interferon Gamma-1B                         | Actimmune                                   |
| Peginterferon Alfa-2A                       | Pegasys                                     |
| Peginterferon Alfa-2B                       | PegIntron<br>Sylatron                       |
| Peginterferon Beta-1A                       | Plegridy                                    |
| Peginterferon alfa-2b/Ribavirin             | PegIntron and Rebetol Combo Pack            |
| <b>Miscellaneous</b>                        |                                             |
| Amphotericin B                              | Amphotericin B                              |
| Amphotericin B Lipid                        | Abelcet                                     |
| Amphotericin B Liposome                     | AmBisome                                    |
| Amphotericin B Cholesteryl Sulfate Complex  | Amphotec                                    |
| Amphotericin B                              | Fungizone                                   |
| Azathioprine                                | Azathioprine<br>Azasan<br>Imuran            |
| Nitrofurantoin                              |                                             |
| Nitrofurantoin                              | Nitrofurantoin<br>Furadantin<br>Furalan     |
| Nitrofurantoin Sodium                       | Ivadantin                                   |
| Nitrofurantoin macrocrystalline             | Nitrofurantoin Macrocrystal<br>Macroclantin |
| Nitrofurantoin monohydrate/macrocrystals    | Nitrofurantoin Monohyd Macro<br>Macrobid    |
| <b>Generic Name (Alias)</b>                 |                                             |
| <b>Study Period: 7/20/2008 to 9/30/2014</b> |                                             |
| <b>Product Name</b>                         |                                             |
| <b>Low Risk Categories</b>                  |                                             |
| <b>Antimicrobial Medications</b>            |                                             |
| Ethambutol HCL                              | Ethambutol HCL                              |

|                                              |                                                                                             |
|----------------------------------------------|---------------------------------------------------------------------------------------------|
|                                              | Myambutol                                                                                   |
| Isoniazid (Isonicotinic acid hydrazide; INH) | Isoniazid<br>Dow-Isoniazid<br>Hyzyd<br>INH<br>Laniazid<br>Nydrazid<br>Rimifon<br>Stanozide  |
| Isoniazid/Rifampin                           | Rifamate                                                                                    |
| Isoniazid/Pyrazinamide/Rifampin              | Isoniazid/Rifampin                                                                          |
| Minocycline                                  | Rifater                                                                                     |
|                                              | Minocycline HCL<br>Arestin<br>Dynacin<br>Minocin<br>Solodyn<br>Ximino                       |
| Sulfasalazine                                | Sulfasalazine<br>Azulfidine<br>Azulfidine EN-tabs<br>Sulfazine<br>Sulfazine EC<br>S.A.S.500 |
| <b>Cardiovascular Agents</b>                 |                                                                                             |
| ACE inhibitors                               |                                                                                             |
| Benazepril HCL                               | Benazepril HCL<br>Lotensin                                                                  |
| Amlodipine Besylate/Benazepril HCL           | Amlodipine besylate/Benazepril HCL<br>Lotrel                                                |
| Captopril                                    | Captopril<br>Capoten                                                                        |
| Enalapril Maleate Oral                       | Enalapril Maleate<br>Epaned<br>Vasotec                                                      |
| Enalaprilat                                  | Enalaprilat                                                                                 |
| Enalapril Maleate/Felodipine                 | Lexxel                                                                                      |
| Enalapril Maleate/Diltiazem Malate           | Teczem                                                                                      |
| Fosinopril Sodium                            | Fosinopril Sodium<br>Monopril                                                               |
| Lisinopril                                   | Lisinopril<br>Prinivil<br>Zestril                                                           |
| Moexipril HCL                                | Moexipril HCL<br>Univasc                                                                    |
| Perindopril Erbumine                         | Perindopril Erbumine<br>Aceon                                                               |
| Quinapril HCL                                | Quinapril HCL<br>Accupril                                                                   |
| Ramipril                                     | Ramipril<br>Altace                                                                          |
| Trandolapril                                 | Trandolapril                                                                                |

|                               |                                                                                                 |
|-------------------------------|-------------------------------------------------------------------------------------------------|
| Trandolapril/Verapamil HCL    | Mavik<br>Tarka<br>Trandolapril/Verapamil HCL                                                    |
| Amiodarone HCL                | Amiodarone HCL<br>Cordarone<br>Nexterone<br>Pacerone                                            |
| <b>Anticoagulants</b>         |                                                                                                 |
| Apixaban                      | Eliquis                                                                                         |
| Dabigatran Etexilate Mesylate | Pradaxa                                                                                         |
| Vorapaxar Sulfate             | Zontivity                                                                                       |
| Rivaroxaban                   | Xarelto<br>Xarelto Starter Pack                                                                 |
| Warfarin Sodium Oral          | Warfarin Sodium<br>Athrombin<br>Athrombin K<br>Coumadin<br>Jantoven<br>Panwarfin<br>Athrombin K |
| Warfarin Potassium            | Athrombin K                                                                                     |
| Ticagrelor                    | Brilinta                                                                                        |
| <b>Beta Blockers</b>          |                                                                                                 |
| Acebutolol HCL                | Acebutolol HCL<br>Sectral                                                                       |
| Atenolol                      | Atenolol<br>Tenormin                                                                            |
| Betaxolol HCL                 | Betaxolol HCL<br>Kerlone                                                                        |
| Bisoprolol Fumarate           | Bisoprolol Fumarate<br>Zebeta<br>Cartrol                                                        |
| Carteolol HCL                 | Cartrol                                                                                         |
| Carvedilol                    | Carvedilol<br>Coreg<br>Coreg CR                                                                 |
| Carvedilol Phosphate          | Coreg CR                                                                                        |
| Esmolol HCL                   | Esmolol HCL<br>Brevibloc                                                                        |
| Labetalol HCL                 | Labetalol HCL<br>Normodyne<br>Trandate                                                          |
| Metoprolol                    |                                                                                                 |
| Metoprolol Succinate          | Metoprolol Succinate<br>Toprol XL                                                               |
| Metoprolol Tartrate           | Metoprolol Tartrate<br>Lopressor                                                                |
| Nadolol                       | Nadolol<br>Corgard                                                                              |
| Nebivolol HCL                 | Nebivolol HCL<br>Bystolic                                                                       |
| Penbutolol Sulfate            | Levatol                                                                                         |
| Pindolol                      | Pindolol<br>Visken                                                                              |

|                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Propranolol HCL                                                    | Propranolol HCL<br>Hemangeol<br>Inderal LA<br>Inderal XL<br>InnoPran XL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Timolol Maleate                                                    | Timolol Maleate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Flecainide Acetate                                                 | Flecainide Acetate<br>Tambocor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Hydralazine HCL                                                    | Hydralazine HCL<br>Dralzine<br>Apresoline<br>BiDil<br>Cam-Ap-Es<br>Hydralazine/Hydrochlorothiazide/Reserpine<br>Hydrap-ES<br>Hydroserpine plus (r-h-h)<br>SER-A-GEN<br>SER-AP-ES<br>Unipres<br>Hydralazine/Reserpine<br>Dralserp<br>Serpasil-Apresoline                                                                                                                                                                                                                                                                                                                                                                                                   |
| Hydrochlorothiazide                                                | Esidrix<br>Hydrochlorothiazide<br>Hydro-D<br>Hydrodiuril<br>Microzide<br>Oretic<br>Zide<br>Aldactazide<br>Spironolactone/Hydrochlorothiazide<br>Methyldopa/Hydrochlorothiazide<br>Aldoril<br>Methyldopa/Hydrochlorothiazide<br>Amiloride HCL/Hydrochlorothiazide<br>Hydro-ride<br>Moduretic<br>Amlodipine/ Valsartan/Hydrochlorothiazide<br>Tekturna HCT<br>Amturnide<br>Atacand HCT<br>Candesartan Cilexetil/Hydrochlorothiazide<br>Avalide<br>Irbesartan/Hydrochlorothiazide<br>Benicar HCT<br>Diovan HCT<br>Valsartan/Hydrochlorothiazide<br>Dyazide<br>Maxzide<br>Triamterene/Hydrochlorothiazide<br>Esimil<br>Exforge HCT<br>H.R.-50<br>Hydro-Reserp |
| Spironolactone/Hydrochlorothiazide                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Methyldopa/Hydrochlorothiazide                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Amiloride HCL/Hydrochlorothiazide                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Amlodipine/ Valsartan/Hydrochlorothiazide                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Aliskiren Hemifumarate/Hydrochlorothiazide                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Aliskiren Hemifumarate/Amlodipine Besylate/<br>Hydrochlorothiazide |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Candesartan Cilexetil/Hydrochlorothiazide                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Irbesartan/Hydrochlorothiazide                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Olmesartan Medoxomil/Hydrochlorothiazide                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Valsartan/Hydrochlorothiazide                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Triamterene/Hydrochlorothiazide                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Guanethidine monosulfate/Hydrochlorothiazide                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Amlodipine/Valsartan/Hydrochlorothiazide                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Hydrochlorothiazide/Reserpine                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

|                                                         |                                                                                               |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Losartan Potassium/Hydrochlorothiazide                  | Hydro-serp<br>Hydropres<br>Hyzaar<br>Losartan Potassium/Hydrochlorothiazide                   |
| Telmisartan/Hydrochlorothiazide                         | Micardis HCT<br>Telmisartan/Hydrochlorothiazide                                               |
| Deserpidine/Hydrochlorothiazide                         | Oreticyl<br>Oreticyl Forte                                                                    |
| Eprosartan Mesylate/Hydrochlorothiazide                 | Teveten HCT                                                                                   |
| Olmesartan Medoxomil / Amlodipine / Hydrochlorothiazide | Tribenzor                                                                                     |
| Procainamide HCL                                        | Procainamide HCL<br>Procan<br>Procan SR<br>Procanbid<br>Procapan<br>Pronestyl<br>Pronestyl-SR |
| Tocainide                                               | Tonocard                                                                                      |
| <b>ACE inhibitors/ Hydrochlorothiazide</b>              |                                                                                               |
| Benazepril HCL/Hydrochlorothiazide                      | Benazepril HCL/Hydrochlorothiazide<br>Lotensin HCT                                            |
| Captopril/Hydrochlorothiazide                           | Captopril/Hydrochlorothiazide<br>Capozide                                                     |
| Enalapril Maleate/Hydrochlorothiazide                   | Enalapril Maleate/Hydrochlorothiazide<br>Vaseretic                                            |
| Fosinopril Sodium//Hydrochlorothiazide                  | Fosinopril Sodium//Hydrochlorothiazide<br>Monopril HCT                                        |
| Lisinopril/Hydrochlorothiazide                          | Lisinopril/Hydrochlorothiazide<br>Prinzide<br>Zestoretic                                      |
| Moexipril HCL/Hydrochlorothiazide                       | Moexipril HCL/Hydrochlorothiazide<br>Uniretic                                                 |
| Quinapril HCL/Hydrochlorothiazide                       | Quinapril HCL/Hydrochlorothiazide<br>Accuretic<br>Quinaretic                                  |
| <b>Beta Blockers/Thiazide Diuretics</b>                 |                                                                                               |
| Atenolol/Chlorthalidone                                 | Atenolol/Chlorthalidone<br>Tenoretic 50                                                       |
| Betaxolol HCL/Chlorthalidone                            | Kerledex                                                                                      |
| Bisoprolol Fumarate/Hydrochlorothiazide                 | Bisoprolol Fumarate/Hydrochlorothiazide<br>Ziac                                               |
| Labetalol HCL/Hydrochlorothiazide                       | Normozide<br>Trandate HCT                                                                     |
| Metoprolol Succinate/Hydrochlorothiazide                | Dutoprol                                                                                      |
| Metoprolol Tartrate/Chlorthalidone                      | Lopressidone                                                                                  |
| Metoprolol Tartrate/Hydrochlorothiazide                 | Metoprolol Tartrate/Hydrochlorothiazide<br>Lopressor HCT                                      |
| Nadolol/Bendroflumethiazide                             | Nadolol/Bendroflumethiazide<br>Corzide                                                        |
| Pindolol/Hydrochlorothiazide                            | Viskazine                                                                                     |
| Propranolol HCL/Hydrochlorothiazide                     | Propranolol HCL/Hydrochlorothiazide                                                           |

|                                     |                    |
|-------------------------------------|--------------------|
|                                     | Inderide           |
|                                     | Inderide LA        |
| Timolol Maleate/Hydrochlorothiazide | Timolide 10-25     |
| Hydralazine/Hydrochlorothiazide     | Hydra-Zide         |
|                                     | Apresoline-Esidrix |
| <b>Miscellaneous</b>                |                    |
| Phentermine HCL                     | Adipex-P           |
|                                     | Fastin             |
|                                     | Obestin-30         |
|                                     | Oby-Trim           |
|                                     | Ona-Mast           |
|                                     | Phentermine HCL    |
|                                     | Suprenza           |
|                                     | Tora               |
|                                     | Wilpo              |

## High Risk Categories

### Anti-Inflammatory Medications

|                                 |                      |
|---------------------------------|----------------------|
| Gold                            |                      |
| Gold Sodium Thiomalate          | Myochrysine          |
| Auranofin (29% Gold)            | Ridaura              |
| Methotrexate (Ametopterin; MTX) | Methotrexate         |
|                                 | Abitrexate           |
|                                 | Folex PFS            |
|                                 | Mexate-AQ Preserved  |
|                                 | Mexate               |
|                                 | Rheumatrex Dose Pack |
|                                 | Otrexup              |
|                                 | Rasuvo               |
|                                 | Trexall              |
| Penicillamine                   | Cuprimine            |
|                                 | Depen Titratabs      |

### Monoclonal Antibodies- Antineoplastics

|             |           |
|-------------|-----------|
| Alemtuzumab | Campath   |
|             | Lemtrada  |
| Bevacizumab | Avastin   |
| Cetuximab   | Erbitux   |
| Rituximab   | Rituxan   |
| Trastuzumab | Herceptin |

### Tumor Necrosis Factor-alpha (TNF $\alpha$ ) blockers

|                                     |                                |
|-------------------------------------|--------------------------------|
| Adalimumab                          | Humira                         |
| Certolizumab Pegol                  | Cimzia (Prefilled/Starter Kit) |
| Etanercept                          | Enbrel                         |
| Golimumab                           | Simponi                        |
|                                     | Simponi Aria                   |
| Infliximab                          | Remicade                       |
| Immune Globulin Intravenous (Human) | Bivigam                        |
|                                     | Carimune NF                    |
|                                     | Flebogamma DIF                 |
|                                     | Gammagard S/D                  |
|                                     | Gammagard S/D Less IgA         |

|                                                     |                                                                                       |
|-----------------------------------------------------|---------------------------------------------------------------------------------------|
|                                                     | Gammaflex<br>Octagam                                                                  |
| <b>Chemotherapeutic Agents</b>                      |                                                                                       |
| Bicalutamide                                        | Bicalutamide<br>Casodex                                                               |
| Bleomycin Sulfate                                   | Bleomycin Sulfate<br>Blenoxane                                                        |
| Busulfan                                            | Busulfex<br>Myleran                                                                   |
| Carboplatin                                         | Carboplatin                                                                           |
| Capecitabine                                        | Capecitabine<br>Xeloda                                                                |
| Carmustine (BCNU)<br>Carmustine in Polifeprosan     | BiCNU<br>Gliadel Wafer                                                                |
| Chlorambucil                                        | Leukeran                                                                              |
| Cisplatin (CDDP)                                    | Cisplatin<br>Platinol                                                                 |
| Cyclophosphamide                                    | Cyclophosphamide<br>Cytosan<br>Neosar                                                 |
| Cytarabine<br>Cytarabine Liposome                   | Cytarabine<br>Cytosar-U<br>DepoCyt                                                    |
| Doxorubicin HCl                                     | Adriamycin PFS<br>Doxil (Liposomal)<br>Doxorubicin HCL<br>Doxorubicin HCL (liposomal) |
| Erlotinib                                           | Erlotinib HCL<br>Tarceva                                                              |
| Etoposide<br>Etoposide Phosphate                    | Etoposide<br>Toposar<br>VePesid<br>Etopophos                                          |
| Floxuridine                                         | Floxuridine<br>FUDR                                                                   |
| Fludarabine Phosphate                               | Fludara<br>Fludarabine Phosphate<br>Oforta                                            |
| Fluorouracil                                        | Adrucil<br>Fluorouracil                                                               |
| Flutamide                                           | Flutamide<br>Eulexin                                                                  |
| Imatinib Mesylate                                   | Gleevec                                                                               |
| Interleukin 2<br>Aldesleukin<br>Denileukin diftitox | Proleukin<br>Ontak                                                                    |
| Lomustine (CCNU)                                    | Lomustine<br>Gleostine                                                                |
| Melphalan HCL (Phenylalanine mustard)               | Melphalan HCL<br>Alkeran                                                              |
| Mercaptopurine                                      | Mercaptopurine<br>Purinethol                                                          |



|                                            |                                            |
|--------------------------------------------|--------------------------------------------|
|                                            | Purixan                                    |
| Semustin                                   | Methyl-CCNU                                |
| Mitomycin (Mitomycin-C; MTC)               | Mitomycin<br>Mitozytrex<br>Mutamycin       |
| Paclitaxel                                 | Abraxane<br>Paclitaxel<br>Taxol            |
| Procarbazine                               | Matulane                                   |
| Vinblastine Sulfate (VLB)                  | Vinblastine Sulfate                        |
| <b>Interferon Therapy</b>                  |                                            |
| Interferon Alfa -2B                        | Intron A                                   |
| Interferon Alfa- N3                        | Alferon N                                  |
| Interferon Alfacon-1                       | Infergen                                   |
| Interferon Beta-1A                         | Avonex<br>Rebif                            |
| Interferon Beta-1B                         | Betaseron<br>Extavia                       |
| Interferon Gamma-1B                        | Actimmune                                  |
| Peginterferon Alfa-2A                      | Pegasys                                    |
| Peginterferon Alfa-2B                      | PegIntron<br>Sylatron                      |
| Peginterferon Beta-1A                      | Plegridy                                   |
| Peginterferon alfa-2b/Ribavirin            | PegIntron and Rebetol Combo Pack           |
| <b>Miscellaneous</b>                       |                                            |
| Amphotericin B                             | Amphotericin B                             |
| Amphotericin B Lipid                       | Abelcet                                    |
| Amphotericin B Liposome                    | AmBisome                                   |
| Amphotericin B Cholesteryl Sulfate Complex | Amphotec                                   |
| Amphotericin B                             | Fungizone                                  |
| Azathioprine                               | Azathioprine<br>Azasan<br>Imuran           |
| Nitrofurantoin                             |                                            |
| Nitrofurantoin                             | Nitrofurantoin<br>Furadantin<br>Furalan    |
| Nitrofurantoin Sodium                      | Ivadantin                                  |
| Nitrofurantoin macrocrystalline            | Nitrofurantoin Macrocrystal<br>Macrodantin |
| Nitrofurantoin monohydrate/macrocrystals   | Nitrofurantoin Monohyd Macro<br>Macrobid   |

|                                                         |                                                                                                              |
|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Pindolol                                                | Pindolol<br>Visken                                                                                           |
| Propranolol HCL                                         | Propranolol HCL<br>Hemangeol<br>Inderal LA<br>Inderal XL<br>InnoPran XL                                      |
| Timolol Maleate                                         | Timolol Maleate                                                                                              |
| Flecainide Acetate                                      | Flecainide Acetate<br>Tambocor                                                                               |
| Hydralazine HCL                                         | Hydralazine HCL<br>Dralzine<br>Apresoline                                                                    |
| Hydrochlorothiazide                                     | Esidrix<br>Hydrochlorothiazide<br>Hydro-D<br>Hydrodiuril<br>Microzide<br>Oretic<br>Zide                      |
| Procainamide HCL                                        | Procainamide HCL<br>Procan<br>Procan SR<br>Procanbid<br>Procapan<br>Pronestyl<br>Pronestyl-SR                |
| Tocainide                                               | Tonocard                                                                                                     |
| <a href="#">ACE inhibitors/ Hydrochlorothiazide</a>     |                                                                                                              |
| <a href="#">Benazepril HCL/Hydrochlorothiazide</a>      | <a href="#">Benazepril HCL/Hydrochlorothiazide</a><br><a href="#">Lotensin HCT</a>                           |
| <a href="#">Captopril/Hydrochlorothiazide</a>           | <a href="#">Captopril/Hydrochlorothiazide</a><br><a href="#">Capozide</a>                                    |
| <a href="#">Enalapril Maleate/Hydrochlorothiazide</a>   | <a href="#">Enalapril Maleate/Hydrochlorothiazide</a><br><a href="#">Vaseretic</a>                           |
| <a href="#">Fosinopril Sodium//Hydrochlorothiazide</a>  | <a href="#">Fosinopril Sodium//Hydrochlorothiazide</a><br><a href="#">Monopril HCT</a>                       |
| <a href="#">Lisinopril/Hydrochlorothiazide</a>          | <a href="#">Lisinopril/Hydrochlorothiazide</a><br><a href="#">Prinzide</a><br><a href="#">Zestoretic</a>     |
| <a href="#">Moexipril HCL/Hydrochlorothiazide</a>       | <a href="#">Moexipril HCL/Hydrochlorothiazide</a><br><a href="#">Uniretic</a>                                |
| <a href="#">Quinapril HCL/Hydrochlorothiazide</a>       | <a href="#">Quinapril HCL/Hydrochlorothiazide</a><br><a href="#">Accuretic</a><br><a href="#">Quinaretic</a> |
| <a href="#">Beta Blockers/Thiazide Diuretics</a>        |                                                                                                              |
| <a href="#">Atenolol/Chlorthalidone</a>                 | <a href="#">Atenolol/Chlorthalidone</a><br><a href="#">Tenoretic 50</a>                                      |
| <a href="#">Bisoprolol Fumarate/Hydrochlorothiazide</a> | <a href="#">Bisoprolol Fumarate/Hydrochlorothiazide</a><br><a href="#">Ziac</a>                              |
| <a href="#">Labetalol HCL/Hydrochlorothiazide</a>       | <a href="#">Normozide</a>                                                                                    |

|                                                          |                                                                                                                                                                                                                                                          |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                          | Trandate HCT                                                                                                                                                                                                                                             |
| <a href="#">Metoprolol Succinate/Hydrochlorothiazide</a> | <a href="#">Dutoprol</a>                                                                                                                                                                                                                                 |
| Metoprolol Tartrate/Hydrochlorothiazide                  | Metoprolol<br>Tartrate/Hydrochlorothiazide<br>Lopressor HCT                                                                                                                                                                                              |
| Nadolol/Bendroflumethiazide                              | Nadolol/Bendroflumethiazide<br>Corzide                                                                                                                                                                                                                   |
| <a href="#">Pindolol/Hydrochlorothiazide</a>             | <a href="#">Viskazide</a>                                                                                                                                                                                                                                |
| Propranolol HCL/Hydrochlorothiazide                      | Propranolol HCL/Hydrochlorothiazide<br>Inderide<br>Inderide LA                                                                                                                                                                                           |
| Timolol Maleate/Hydrochlorothiazide                      | Timolide 10-25                                                                                                                                                                                                                                           |
| <a href="#">Hydralazine/Hydrochlorothiazide</a>          | <a href="#">Hydra-Zide</a><br><a href="#">Apresoline-Esidrix</a>                                                                                                                                                                                         |
| <b>Miscellaneous</b>                                     |                                                                                                                                                                                                                                                          |
| <a href="#">Phentermine HCL</a>                          | <a href="#">Adipex-P</a><br><a href="#">Fastin</a><br><a href="#">Obestin-30</a><br><a href="#">Oby-Trim</a><br><a href="#">Ona-Mast</a><br><a href="#">Phentermine HCL</a><br><a href="#">Suprenza</a><br><a href="#">Tora</a><br><a href="#">Wilpo</a> |
| <b>High Risk Categories</b>                              |                                                                                                                                                                                                                                                          |
| <b>Anti-Inflammatory Medications</b>                     |                                                                                                                                                                                                                                                          |
| Gold                                                     |                                                                                                                                                                                                                                                          |
| Gold Sodium Thiomalate<br>Auranofin (29% Gold)           | Myochrysine<br>Ridaura                                                                                                                                                                                                                                   |
| Methotrexate (Amethopterin; MTX)                         | Methotrexate<br>Abitrexate<br>Folex PFS<br>Mexate-AQ Preserved<br>Mexate<br>Rheumatrex Dose Pack<br>Otrexup<br>Rasuvo<br>Trexall                                                                                                                         |
| Penicillamine                                            | Cuprimine<br>Depen Titratabs                                                                                                                                                                                                                             |
| <b>Monoclonal Antibodies- Antineoplastics</b>            |                                                                                                                                                                                                                                                          |
| Alemtuzumab                                              | Campath<br>Lemtrada                                                                                                                                                                                                                                      |
| Bevacizumab                                              | Avastin                                                                                                                                                                                                                                                  |
| Cetuximab                                                | Erbitux                                                                                                                                                                                                                                                  |
| Rituximab                                                | Rituxan                                                                                                                                                                                                                                                  |
| Trastuzumab                                              | Herceptin                                                                                                                                                                                                                                                |

|                                                    |                                                                                                             |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Tumor Necrosis Factor-alpha (TNFα) blockers</b> |                                                                                                             |
| Adalimumab                                         | Humira                                                                                                      |
| Certolizumab Pegol                                 | Cimzia (Prefilled/Starter Kit)                                                                              |
| Etanercept                                         | Enbrel                                                                                                      |
| Golimumab                                          | Simponi<br>Simponi Aria                                                                                     |
| Infliximab                                         | Remicade                                                                                                    |
| Immune Globulin Intravenous (Human)                | Bivigam<br>Carimune NF<br>Flebogamma DIF<br>Gammagard S/D<br>Gammagard S/D Less IgA<br>Gammaplex<br>Octagam |
| <b>Chemotherapeutic Agents</b>                     |                                                                                                             |
| Bicalutamide                                       | Bicalutamide<br>Casodex                                                                                     |
| Bleomycin Sulfate                                  | Bleomycin Sulfate<br>Blenoxane                                                                              |
| Busulfan                                           | Busulfex<br>Myleran                                                                                         |
| Carboplatin                                        | Carboplatin                                                                                                 |
| Capecitabine                                       | Capecitabine<br>Xeloda                                                                                      |
| Carmustine (BCNU)<br>Carmustine in Polifeprosan    | BiCNU<br>Gliadel Wafer                                                                                      |
| Chlorambucil                                       | Leukeran                                                                                                    |
| Cisplatin (CDDP)                                   | Cisplatin<br>Platinol                                                                                       |
| Cyclophosphamide                                   | Cyclophosphamide<br>Cytosan<br>Neosar                                                                       |
| Cytarabine<br><br>Cytarabine Liposome              | Cytarabine<br>Cytosar-U<br>DepoCyt                                                                          |
| Doxorubicin HCl                                    | Adriamycin PFS<br>Doxil (Liposomal)<br>Doxorubicin HCL<br>Doxorubicin HCL (liposomal)                       |
| Erlotinib                                          | Erlotinib HCL<br>Tarceva                                                                                    |
| Etoposide<br><br>Etoposide Phosphate               | Etoposide<br>Toposar<br>VePesid<br>Etopophos                                                                |
| Floxuridine                                        | Floxuridine<br>FUDR                                                                                         |
| Fludarabine Phosphate                              | Fludara<br>Fludarabine Phosphate<br>Oforta                                                                  |
| Fluorouracil                                       | Adrucil<br>Fluorouracil                                                                                     |

|                                                     |                                         |
|-----------------------------------------------------|-----------------------------------------|
| Flutamide                                           | Flutamide<br>Eulexin                    |
| Imatinib Mesylate                                   | Gleevec                                 |
| Interleukin 2<br>Aldesleukin<br>Denileukin diftitox | Proleukin<br>Ontak                      |
| Lomustine (CCNU)                                    | Lomustine<br>Gleostine                  |
| Melphalan HCL (Phenylalanine mustard)               | Melphalan HCL<br>Akeran                 |
| Mercaptopurine                                      | Mercaptopurine<br>Purinethol<br>Purixan |
| Semustin                                            | Methyl-CCNU                             |
| Mitomycin (Mitomycin-C; MTC)                        | Mitomycin<br>Mitozytrex<br>Mutamycin    |
| Paclitaxel                                          | Abraxane<br>Paclitaxel<br>Taxol         |
| Procarbazine                                        | Matulane                                |
| Vinblastine Sulfate (VLB)                           | Vinblastine Sulfate                     |
| <b>Interferon Therapy</b>                           |                                         |
| Interferon Alfa -2B                                 | Intron A                                |
| Interferon Alfa- N3                                 | Alferon N                               |
| Interferon Alfacon-1                                | Infergen                                |
| Interferon Beta-1A                                  | Avonex<br>Rebif                         |
| Interferon Beta-1B                                  | Betaseron<br>Extavia                    |
| Interferon Gamma-1B                                 | Actimmune                               |
| Peginterferon Alfa-2A                               | Pegasys                                 |
| Peginterferon Alfa-2B                               | PegIntron                               |
| Peginterferon Beta-1A                               | Sylatron<br>Plegridy                    |
| <b>Miscellaneous</b>                                |                                         |
| Amphotericin B                                      | Amphotericin B                          |
| Amphotericin B Lipid                                | Abelcet                                 |
| Amphotericin B Liposome                             | AmBisome                                |
| Amphotericin B Cholesteryl Sulfate Complex          | Amphotec                                |
| Amphotericin B                                      | Fungizone                               |
| Azathioprine                                        | Azathioprine<br>Azasan<br>Imuran        |

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|                                          |                |                              |
|------------------------------------------|----------------|------------------------------|
| Nitrofurantoin                           | Nitrofurantoin | Nitrofurantoin               |
|                                          |                | Furadantin                   |
|                                          |                | Furalan                      |
| Nitrofurantoin Sodium                    |                | Ivadantin                    |
| Nitrofurantoin macrocrystalline          |                | Nitrofurantoin Macrocrystal  |
|                                          |                | Macroclantin                 |
| Nitrofurantoin monohydrate/macrocrystals |                | Nitrofurantoin Monohyd Macro |
|                                          |                | Macrobid                     |

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\* Systemic use only: capsule (hard, soft, etc.); capsule, sustained action; disposable syringe (ml); vial (sdv,mdv or additive) (ml); suspension, reconstituted, oral (ml); tablet; tablet, sustained action; inhalation; transdermal.

Matsuno O. Drug induced interstitial lung disease: mechanisms and best diagnostic approaches. *Respir Res.* 2012;13:39.

Schwaiblmair M, Behr W, Haeckel T, Markl B, Foerg W, Berghaus T. Drug-Induced Interstitial Lung Disease. *The Open Respiratory Medicine Journal.* 2012;6:63-74.

Fernandez AB, KarasRH, Alsheikh-AliAA, ThompsonPD. Statins and Interstitial Lung Disease. *CHEST* 2008; 134:824-830.

CamusP, FantonA, BonniaudP, Camus C FoucherP. Interstitial Lung Disease Induced by Drugs and Radiation. *Respiration* 2004;71:301-326.

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#### History Of Smoking (for sensitivity analysis)

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|        |                                             |
|--------|---------------------------------------------|
| 305.1  | Tobacco Use Disorder                        |
| 649.0  | Tobacco Use Complicat Pregnancy             |
| 649.00 | Tobacco Use Comp Preg Unspecified           |
| 649.01 | Tobacco Use Comp Preg W Delivery            |
| 649.02 | Tobacco Use Comp Preg W Delivery Postpartum |
| 649.03 | Tobacco Use Comp Preg Antepartum            |
| 649.04 | Tobacco Use Comp Preg Postpartum            |
| 989.84 | Toxic Effect Tobacco                        |
| V15.82 | Personal History Of Tobacco Use             |

#### Medication Proxy (Medication dispensed prior to index date)

Bupropion (Zyban)  
Varenicline (Chantix)

## APPENDIX F. SLD Propensity Score Model Development: Selection of Variables

The following variables will all be entered as covariates in the initial logistic regression model used as the starting point for developing a reduced model. The reduced model will be used to calculate propensity scores for patients in the SLD sub-cohort. All variables will be assessed during the baseline period, unless otherwise specified. Specific diagnosis and procedure codes defining covariates marked with an asterisk (\*) are found in **Appendix B.4**. Imbalance after PS matching in variables listed as key risk factors will trigger refitting the PS logistic model and/or explicit control for the variable in the CPH survival analysis models.

### Liver Injury/Disease:

#### **Key risk factors**

- History of Alcoholism\*;
- History of use of hepatotoxic medications\*;
- History of Congestive heart failure\*;
- Number of hospitalizations in acute care facilities<sup>†</sup>;
- Number of different medications (by therapeutic class);

#### **Other risk factors**

- Gender (male=1; female=0);
- Age on index date (Age groups:<50; 50-<60; 60-<70; 70-<80, 80+);
- Days from start of study to patient index date: <180,180-<360;360-<540,540+;
- Number of study medications other than the index drug;
- Use of anti-arrhythmic other than one of the study medications\*;
- History of Bile duct disorders (e.g., primary sclerosing cholangitis)\*;
- History of Obesity;
- History of Diabetes [Diagnosis or anti-diabetic therapy]\*;
- Number of office visits;
- Number of ER visits;
- Gastroenterology specialty visits (1 or more visits=1; no visits=0).

<sup>†</sup> In the DOD data, acute care facilities will be all direct care facilities (i.e., those reported in the SIDR data table) and hospitalizations at facilities with Institution Type of 10 (General medical or surgical), 76 (Skilled nursing facility) or 91 (Sole community) reported in the purchased care data table (TED-I).

## **APPENDIX G. ILD Propensity Score Model Development: Selection of Variables**

The following variables will all be entered as covariates in the initial logistic regression model used as the starting point for developing a reduced model from which propensity scores will be developed for patients in the ILD sub-cohort. All variables will be assessed during the baseline period, unless otherwise specified. Specific diagnosis and procedure codes defining covariates marked with an asterisk (\*) are found in **Appendix E**. Imbalance after PS matching in variables listed as key risk factors will trigger refitting the PS logistic model and/or explicit control for the variable in the CPH survival analysis models.

### **Interstitial Lung Disease:**

#### **Key risk factors**

- History of Exposure to occupational and environmental toxins\*;
- History of Asthma\*;
- History of Chronic obstructive pulmonary disease\*;
- History of Bronchitis (excluding acute bronchitis)\*;
- Prior use of Therapeutic oxygen treatment\*;
- History of Gastroesophageal reflux disease\*;
- History of Connective Tissue Disease\*;
- Number of hospitalizations in acute care facilities<sup>†</sup>;
- Prior use of Agents Associated with Drug Induced Pulmonary Disease (individual drug groups: Antimicrobial medications; Selected Cardiovascular Agents; Anti-Inflammatory Medications; Biologic Medications; Chemotherapy agents; Miscellaneous)\*;
- Pulmonology specialty visits (1 or more visits=1; no visits=0).

#### **Other risk factors**

- Gender (male=1; female=0);
- Age on index date (Age groups:<50; 50-<60; 60-<70; 70-<80, 80+);
- Days from start of study to patient index date ( <180,180-<360;360-<540,540+);
- Number of study medications other than the index drug ;
- Use of anti-arrhythmic other than one of the study medications\*;
- Number of office visits;
- Number of ER visits;



- Number of different medications (by therapeutic class);

<sup>†</sup> In the DOD data, acute care facilities will be all direct care facilities (i.e., those reported in the SIDR data table) and hospitalizations at facilities with Institution Type of 10 (General medical or surgical), 76 (Skilled nursing facility) or 91 (Sole community) reported in the purchased care data table (TED-I).

Note: Self-reported information on exposure to smoking has been found to be unreliable. Therefore History of smoking will not be used as a propensity score model variable. However, a sensitivity analysis will be conducted if sufficient smoking data are available to do so.

- History of Smoking\*; (Look at “Smoking Status” [Demographic variable], separately.)
  - Medication Proxy
    - bupropion (Zyban)
    - varenicline (Chantix)