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The burden of intermittent OCS use in asthma

An observational cohort study to describe intermittent OCS utilisation and its association with adverse outcomes and healthcare resource use and costs in asthma using the OPCRD and CPRD databases.

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation or special term	Explanation
ADEPT	Anonymised Data Ethics & Protocol Transparency Committee
A&E	Accident and Emergency
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical classification system of medication
AZ	AstraZeneca
BEC	Blood Eosinophil Count
BMI	Body Mass Index
BTS	British Thoracic Society
CPRD	Clinical Practice Research Datalink
DDD	Defined daily dose
EMR	Electronic Medical Record
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
FEV_1	Forced Expiratory Flow in one second
FVC	Forced Vital Capacity
GINA	Global Initiative for Asthma
GP	General Practitioner
HES	Hospital Episode Statistics
HRU	Healthcare Resource Utilisation
ICD-10	International Classification of Disease v10
ICS	Inhaled Corticosteroids
ID	Index Date
IQR	Inter Quartile Range
ISAC	Independent Scientific Advisory Committee
LABA	Long Acting β adrenoceptor Agonists
LAMA	Long-Acting Muscarinic Receptor Antagonists
LRTI	Lower Respiratory Tract Infection
LTRA	Leukotriene Receptor Antagonist
NRAD	National Review of Asthma Deaths
NHS	National Health Service
OCS	Oral Corticosteroids

Abbreviation or special term	Explanation
OPC	Optimum Patient Care
OPCRD	Optimum Patient Care Research Database
OPRI	Observational and Pragmatic Research Institute
PEFR	Peak Expiratory Flow
RCP3	Royal College of Physicians 3 Questions for asthma
SABA	Short-Acting Beta-Agonists
SAMA	Short-Acting Muscarinic Antagonist
SCS	Systemic Corticosteroids
SD	Standard Deviation
SIGN	Scottish Intercollegiate Guidelines Network
UK	United Kingdom

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PROTOCOL SYNOPSIS

An observational cohort study to describe intermittent OCS utilisation and its association with adverse outcomes and healthcare resource use and costs in asthma using the OPCRD and CPRD databases.

Background/Rationale:

Oral corticosteroids (OCS) are frequently prescribed for patients with respiratory conditions such as asthma. Despite evidence on the adverse outcomes of OCS, their use remains part of the clinical guidelines for asthma. There is evidence showing that relatively low cumulative doses of OCS can increase the risk of adverse outcomes and there is a wide consensus among physicians and researchers that the use of OCS should be limited to a minimum and should only be used when no other treatment option is available. Despite this OCS are still widely prescribed for patients with mild asthma.

Whilst there is evidence showing increased risk of adverse events related to cumulative OCS dose there is little showing how patterns of intermittent OCS use are related to adverse events and related healthcare costs.

Objectives:

1. To classify intermittent OCS prescriptions for patients with asthma and to describe longitudinal patterns of intermittent (acute) OCS use by Global Initiative for Asthma (GINA) step, and Inhaled Corticosteroids (ICS) and Short-Acting Beta-Agonists (SABA) use.

2. To assess the association between differing patterns of intermittent OCS use and OCS-related adverse events (AE) in patients with asthma

3. To describe the impact of different patterns of intermittent OCS use on the frequency of healthcare resource utilisation (HRU) in patients with asthma.

4. To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up.

Methods:

Study design

The most recent extraction of Electronic Medical Record (EMR) data from Optimum Patient Care Research Database (OPCRD) and Clinical Practice Research Datalink (CPRD) general practices will be used for this analysis. The index date (ID) will be defined for patients aged ≥4 years of age, the ID will be the first acute OCS prescription with concurrent evidence of asthma event (medication, asthma consultation and/or asthma diagnosis) within a 3-month period. The index date will be the patients first prescription of OCS within 3 months, either before or after, an asthma related event (medication, asthma consultation and/or asthma diagnosis). Patients will be excluded if they have ever had a diagnosis of a chronic condition* treated with OCS. Patients will be categorised into OCS prescribing patterns.

Demographics, clinical characteristics, including asthma severity and control and HRU, will be described for different prescribing patterns over their follow up period.

For objective 4, to describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up. These patients will be monitored to determine OCS-related AEs.

Data Source(s)

Optimum Patient Care Research Database (OPCRD) and Clinical Practice Research Datalink (CPRD) with linked Hospital Episode Statistics (HES) data.

Study Population:

Inclusion Criteria

1. OCS Arm - Patients with a prescription of an OCS with a concurrent (within 3 months) asthma event defined as an asthma QOF diagnosis or asthma QOF prescription. This will be the index date.
2. Non-OCS Arm - Patients with no OCS prescription at any time
3. Patients with at least 12 months baseline period (prior to index date)
4. Patients aged 4 or over at the index date

Exclusion Criteria

1. Patients with a diagnosis, ever, for a chronic condition treated with OCS

* Patients aged >=18: Ankylosing spondylitis, Sjogren's syndrome, Systemic lupus erythematosus, Temporal arteritis, Ulcerative colitis, Psoriatic arthritis, Multiple sclerosis, Polymyalgia rheumatica, Crohn's disease, Cancer of respiratory system, Patients aged >4 & <18: Analysis of concurrent OCS and diagnoses will determine exclusion conditions

2. Patients with a chronic AE outcome prior to the index date will be excluded from the analysis. This will ensure that the first chronic condition is the post index date incident event.

Feasibility:

Feasibility of using OCS prescribing patterns was explored in the OPCRD dataset. A total of 653,548 patients met the study criteria stated above. Forty percent of these patients received only one prescription of OCS during their follow-up period, 39% of patients had periods of frequent OCS prescribing (frequent or mixed prescribing including frequent OCS prescription with gaps of less than 90 days). Twenty percent of patients were found to have periods of sporadic OCS prescribing (sporadic or mixed including sporadic OCS prescriptions with gaps of greater than 365 days).

Exposure(s):

Exposure will be defined as an OCS prescription prescribed with a concurrent asthma event. OCS exposures will cease at the time of the patients first AE.

Outcome(s):

Objective 1: Baseline patient characteristics will be collected according to patients OCS patterns of use. These include:

a) patient characteristics described prior to index date
b) length of patient record prior and after index date
c) age of onset of asthma (age at first asthma diagnosis ever)
d) time from first asthma diagnosis date to index date
e) ICS and SABA use in the year prior to index date
f) patient's treatment by Global Initiative for Asthma (GINA) (2020) treatment step prior to index date

Objective 2: The following adverse events for OCS will be studied: type 2 diabetes mellitus, osteoporosis/osteoporotic fractures, hypertension, glaucoma, sleep apnoea, weight gain and depression/anxiety, pneumonia, cataracts, sleep disorders, cardiovascular disease, chronic kidney disease, dyslipidaemia and peptic ulcer disease, and in the adolescent population we will look for growth suppression and behavioural disorders.

Objective 3: Annualised healthcare resource utilisation and related costs will be determined in terms of primary care consultation costs, specialist consultations, hospitalisations, and Accident and Emergency (A&E) attendances.

Objective 4: To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up.

Statistical Analysis:

Objective 1: Baseline characteristics will be described in the baseline period for patients according to their longitudinal patterns of intermittent (acute) OCS use by GINA step, and ICS and SABA use. To describe the distribution of variables among the OCS prescribing patterns.

Objective 2: A matched historical cohort study will be performed with an assessment of potential confounders during a baseline period prior to the index date. Patients will be excluded if they had a record of the adverse event prior to their index date and categorised according to their patterns of OCS prescribing. To address potential differences between OCS groups, patients will be matched initially on gender, age, and the index date. Other potential confounders (listed in 4.1.1) will be identified during the analysis, using potential bias assessments of covariates.

Objective 3: HRU events will be described over the follow up period using the CPRD dataset. HRU events will be described in the baseline period and during the follow up for both asthma-related and all-cause events. CPRD HES linked data will be used to describe hospital admissions, A&E attendances, and Outpatient visits

Objective 4: To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up.

AMENDMENT HISTORY

Date	Section of study protocol		Amendment or update	Reason
06/05/20	Various	v3 -v5	Various (detailed in version with reviewers' comments)	Amendment following MEORT Review
11/08/20	Various	v6.1	Various (detailed in version with reviewers' comments)	Amendment following AZ and RTI review

MILESTONES

Milestone	Planned date
OPCRD Dataset Created	August 2020
Analysis of OPCRD	September 2020
Arrival of CPRD	October 2020
CPRD Dataset created	October 2020
Analysis of CPRD	November 2020
Final Study Report	January 2021

1. BACKGROUND AND RATIONALE

1.1 Background

Asthma currently affects an estimated 358 million individuals worldwide and poses a substantial burden on healthcare systems.[1] Longstanding asthma medications are not optimally used to treat asthma. Patients often receive large numbers of SABA prescriptions despite United Kingdom (UK) asthma guidelines stating use at least three times a week is a marker for potentially poor control and a predictor of future risk of asthma attacks and death.[2] The National Review of Asthma Deaths (NRAD) recommended that prescription of more than one Short-Acting Beta-Agonists (SABA) per month should trigger an asthma review. Underuse of Inhaled Corticosteroids (ICS) has also contributed to asthma deaths.[3] New treatment regimens for patients with asthma are being recommended for both the milder and severe asthma populations, e.g. amendments to GINA treatments steps and the development of biological therapies, respectively. The biological agents mepolizumab, reslizumab and benralizumab which target the interleukin-5 molecules or their receptors to reduce eosinophils have been demonstrated to reduce asthma attacks and improve symptoms in patients with severe, uncontrolled eosinophilic asthma. They also have the potential to reduce patient exposure to high dosages of ICS and oral corticosteroids (OCS) and thereby, OCS related adverse effects.[4-7]

Despite the more widespread use of newer treatment regimens, oral corticosteroids are still widely used in patients with asthma. In a recent systematic literature review, 58 studies reported short-term OCS/Systemic corticosteroid (SCS) use for patients with asthma. Short-term OCS/SCS use ranged from 2.1% (international study of SCS use for patients aged ≥12 years with asthma requiring GINA Step 2 treatment or greater) to 92·6% (U.K. study of OCS use for patients with severe asthma).

Asthma management guidelines recommend the use of oral corticosteroids in the management of severe asthma exacerbations. Chronic or long-term oral corticosteroids can be used as a continuous, or frequent use, for a small number of patients who are not controlled on high-dose ICS therapies. These patients should remain under the care of a specialist asthma service. Intermittent or burst oral steroid are recommended to prevent mortality, relapses, subsequent hospital admission and requirement for β2 agonist therapy. The British Thoracic Society/ Scottish Intercollegiate Guidelines Network (BTS/SIGN) recommends an intermittent OCS dose of 40-50mg prednisolone, daily for a minimum of 5 days and a maintenance dose at the lowest dose providing adequate control.[8] GINA recommends 40-50mg prednisolone, daily for 5-7 days and a maintenance dose of ≤7.5mg.[2]

Systematic literature reviews of studies evaluating the use of OCS show an increased risk of adverse outcomes which increase with dose.[9,10] A recent Observational and Pragmatic Research Institute (OPRI) study examining a broad UK asthma population initiating OCS (including all doses of intermittent and chronic use) over a medium period of over 7 years found that increasing cumulative exposure to OCS places patients at a high risk of OCS-related adverse outcomes ranging from acute complications such as infections to chronic complications such as

metabolic and cardiovascular events. The onset of some outcomes was associated with cumulative OCS exposure of only 0.5–<1 g.[11]

Most epidemiological studies examining the impact of OCS use are inclined to place more emphasis on maintenance OCS use in patients with severe asthma. In clinical practice, however, most patients have mild to moderate disease and it is unclear to what extent intermittent use of OCS will increase the risk of adverse outcomes.[12] A cohort study performed in the UK CPRD reported that over 60% of patients with asthma have mild asthma (British Thoracic Society (BTS) steps ½ [Appendix 8.1]) and that these patients often have suboptimal symptom control. Whilst exacerbation rates increase with severity, 9.3 exacerbations for patients at BTS step 5, this study reported that patients with the mildest asthma (BTS step 1) experienced 2.4 exacerbations per 10 person years.[13] A US longitudinal, open-cohort, observational study using health insurance claims data (1997-2013: Medicaid) from several US states found that a high proportion of mild asthma patients are prescribed intermittent bursts of OCS (1 in 4).[14]

A UK retrospective analysis of patients from 46 GP surgeries examined prescription rates of OCS in relation to asthma treatment steps (according to the BTS Guidelines). This study reported that the mean number of OCS courses per year ranged from 1.2 to 2.1 at Steps 1 to 4, and 5.3 at Step 5 (maintenance OCS therapy).[15]

1.2 OCS Literature Review

A literature review was undertaken to determine how previous studies classified OCS use. Patterns of short-term OCS use are defined by terms such as being ‘intermittent’, ‘acute’, ‘burst’ and ‘for asthma exacerbations’. Long term OCS use have been defined as being ‘daily’, ‘continuous’, ‘maintenance’, ‘chronic’, used as ‘controller medication’ or ‘high use’. This protocol will use the phrase intermittent and maintenance OCS use.

A search of the literature within PubMed to identify English-language articles using the following search terms: “Adrenal Cortex Hormones"[nm][†] AND oral corticosteroid NOT inhalation AND asthma AND (burst OR Intermittent OR Acute). Abstracts and full-text articles were screened to determine their relevance.

The measures used in these studies to classify patients OCS use varied between studies. Methods used to categorise OCS use included:

a) The number of days of continuous OCS prescribing (e.g. from >15 days,[16] => 30days,[17] =>60 days[18], >90 days[19])
b) Periods covered with OCS without gaps (e.g.=<14 days[20])
c) The average number of days covered over a time period (e.g. >=50% of days covered[21])
d) Prescribing instruction including titration patterns (>14 days with no titration pattern[15])
e) Cumulative and Average daily dosage over time periods (≥1600mg/year [4.4mg/d/y][22] and >=2.5mg/d over a year,[23] >=5mg/d over a year[24])

[†] [nm] – Mesh Heading

This literature review found that OCS prescriptions were categorised based on aggregate measures over a time period rather than prescribing patterns. The review suggested that cumulative OCS/SCS exposure may not be an ideal measure because of possible variations among patients with regard to factors such as disease duration and severity.[25] This study intends to improve by firstly categorise OCS prescriptions as being intermittent or maintenance use based upon prescribing information including dosing instructions, daily dose, tablet strength, concurrent diagnoses and asthma medications, number of scripts per year, and other concurrent asthma medication.

In addition to the prescribing information the patient's asthma treatments will be extracted and categorised into GINA 2020 treatment steps (appendix 8.2). Patients at GINA step 5 receiving OCS would therefore be expected to be in receipt of maintenance OCS.

Secondly, patients receiving intermittent OCS prescriptions will be categorised according to the patterns of prescribing rather than the average dose or number of prescriptions over a time period.

1.3 Rationale

Systematic literature reviews of studies evaluating the use of OCS show an increased risk of adverse outcomes which increase in dose.[9,10] A recent OPRI study examining a broad UK asthma population initiating OCS the onset of some outcomes was associated with cumulative OCS exposure starting at 0.5–<1 g.10, however there was no evidence on whether patients with intermittent use are associated with adverse outcomes and associated increased healthcare resource costs.

1.4 Feasibility

Initial analysis to better understand which OCS patterns should be considered for use in this analysis reported patterns for patients meeting the inclusion and exclusion criteria and receiving intermittent OCS prescriptions within OPCRD.

Prescribing of OCS were categorised as either a) one off – patients with only one OCS prescription, b) sporadic – prescriptions with gaps 365 days or over, c) Infrequent – prescription with gaps of between 182 – 365 days, d) Moderately infrequent - prescription with gaps of between 90 and 182 days, e) Frequent – prescription gaps of less than 90 days and f) Mixed – Patients with a mixture of the patters listed above.

Most patients were found to have either one off OCS prescriptions or mixed patterns (Table 1).

Table 1 - OCS Prescribing patterns for patients in OPCRD

Prescribing Patterns	Numbers of Patients	%
One Off	263,430	40.3%
Frequent or Mixed prescribing including frequent	256,866	39.3%
Sporadic or Mixed including sporadic	130,605	20.0%
Only Infrequent	1,685	0.3%
Only Moderately Frequent	871	0.1%
Total	653,457	

2. OBJECTIVES AND HYPOTHESES

2.1 Hypothesis

Patients with a more frequent OCS prescribing patterns will suffer an increase in adverse events and increased healthcare costs.

2.2 Primary Objective(s) & Hypothesis(es)

1. To classify intermittent OCS prescriptions for patients with asthma and to describe longitudinal patterns of intermittent (acute) OCS use by GINA step, and ICS and SABA use.
2. To assess the association between patterns of intermittent OCS use and OCS-related adverse outcomes in patients with asthma.
3. To describe the impact of different patterns of intermittent OCS use on the frequency of healthcare resource utilisation in patients with asthma.
4. To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up. The index date will be the patients first prescription of OCS within 3 months, either before or after, an asthma related event (medication, asthma consultation and/or asthma diagnosis)

3. METHODOLOGY

3.1 Study Design

3.1.1 Data Sources

A historical longitudinal descriptive cohort study using patients' electronic medical records extracted from general practices from the Optimum Patient Care Research Database (OPCRD) and Clinical Practice Research Datalink (CPRD).

The OPCRD comprises data extracted through the Optimum Patient Care (OPC) Clinical Service Evaluation. At the time of writing, OPCRD contains anonymized, research-quality data for approximately 7 million patients across the UK. Dates of last data collection from

general practices range from 2008 to 2019, with almost half of the data being uploaded in 2019 and 79% in the last 5 years.[26]

The CPRD database is an ongoing primary care database of anonymized medical records from general practitioners, with coverage of over 11 million patients from 674 practices in the UK.[27] At the time of writing CPRD HES linked data is available up to a maximum of March 2019.

A practice-based quality marker, the "up-to-standard date", is generated by the CPRD for each subscribing practice and data subsequent to the practice up-to-standard date are considered to be acceptable, research quality, prospectively recorded data. The CPRD is well-validated and used frequently for medical and health research.

The CPRD records will be linked to Hospital Episode Statistics (HES), which records all utilization of UK hospitals.[27] This allows identification of any hospital admission, including admissions with asthma as the primary diagnosis. In addition, data is linked to HES outpatient data to identify outpatient visits and to HES A&E data to identify emergency department attendances.

For objective 3, only CPRD data will be used to describe HRU.

The OPCRD database is approved by the Health Research Authority for clinical research use (Research Ethics Committee reference: 15/EM/0150), is governed by the Anonymised Data Ethics & Protocol Transparency (ADEPT) Committee, and offers a high-quality data source that is used regularly in clinical, epidemiological and pharmaceutical research. CPRD database access will require approval from Independent Scientific Advisory Committee (ISAC).

3.2 Inclusion Criteria

3.2.1 Inclusion Criteria

1. OCS Arm - Patients with a prescription of an OCS with a concurrent (within 3 months) asthma event defined as an asthma QOF diagnosis or asthma QOF prescription. This will be the index date.
2. Non-OCS Arm - Patients with no OCS prescription at any time
3. Patients with at least 12 months baseline period (prior to index date)
4. Patients aged 4 or over at the index date

3.2.2 Exclusion Criteria

1. Patients with a diagnosis, ever, for a chronic condition treated with OCS[‡§]

[‡] For patients aged >=18 Ankylosing spondylitis, Sjogren's syndrome, Systemic lupus erythematosus, Temporal arteritis, Ulcerative colitis, Psoriatic arthritis, Multiple sclerosis, Polymyalgia rheumatica, Crohn's disease, Cancer of respiratory system

[§] Patients aged >4 & <18: Analysis of concurrent OCS and diagnoses will determine exclusion conditions

2. Patients with a chronic AE outcome prior to the index date will be excluded from the analysis. This will ensure that the first chronic condition is the post index date incident event.

3.3 Study Design

Objective 1: To classify intermittent OCS prescriptions for patients with asthma and to describe longitudinal patterns of intermittent (acute) OCS use by Global Initiative for Asthma (GINA) step, and Inhaled Corticosteroids (ICS) and Short-Acting Beta-Agonists (SABA) use.

A historical follow-up study will be performed including a broad real-life population of patients with active asthma, registered at GP practices in the UK, using combined data from the OPCRD and the CPRD.

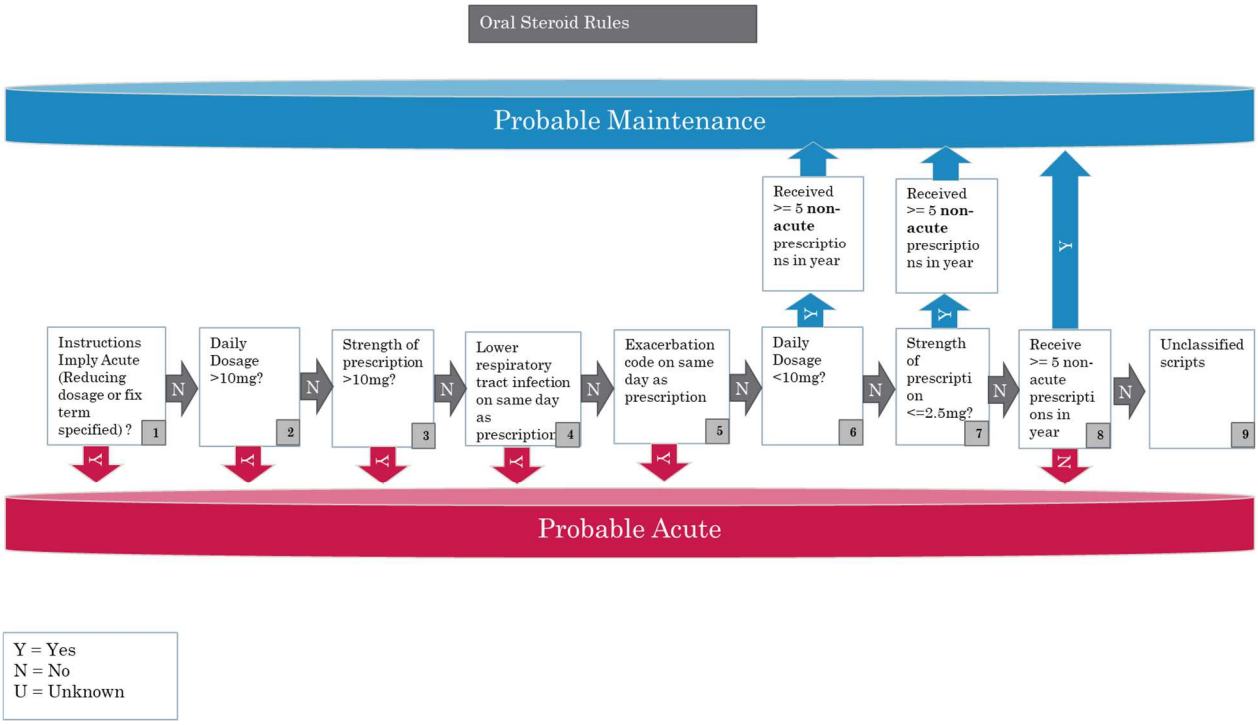
The OPCRD and CPRD datasets will be constructed separately and patients with duplicate data will be excluded before pooling for analyses. These two databases have been combined in multiple prior and current studies conducted by OPRI (Price et al., 2015; Israel et al., 2015; Roche et al., 2015).[28-30] Hence, OPRI has expertise in identifying duplicate records of patients who are present in both OPCRD and CPRD datasets (estimated to be in 2% of cases) by matching on a number of variables, such as the year of birth, gender and index date.

As CPRD and OPCRD may contain identical data from a subset of patients extracted from the same primary care practice EMR systems, there is a risk of patient duplication. CPRD GOLD, which is the database to which we have requested access contains data from practices using Vision software only; OPCRD contains data from a range of software providers including EMIS, iSoft, Microtest, SystemOne and Vision. For this study, we will take a conservative approach and drop all data from Vision practices from the OPCRD database prior to commencing the study, to completely avoid overlap of GP practices with CPRD. Vision data constitutes about 12% of the OPRD database so we do not anticipate this will have a significant impact on final patient numbers.

Study inclusion and exclusion criteria listed above will be used to select the study population. Patients OCS prescriptions will then be classified as acute using an existing OPRI OCS algorithm (Figure 1).

The OPRI OCS algorithm uses information associated to the OCS prescriptions to determine whether they were likely an acute/intermittent or a maintenance script. This is done in a stepwise approach using the most definitive information first e.g. the dosing instructions. For prescriptions that do not enable a decision using the dosing instructions the next most definitive information is used, this being the daily dose. This approach has been used in previous OPRI studies to determine intermittent/maintenance OCS prescribing.

Figure 1 – OPRI OCS Algorithm to classify acute & maintenance (doses represent Prednisolone equivalent)

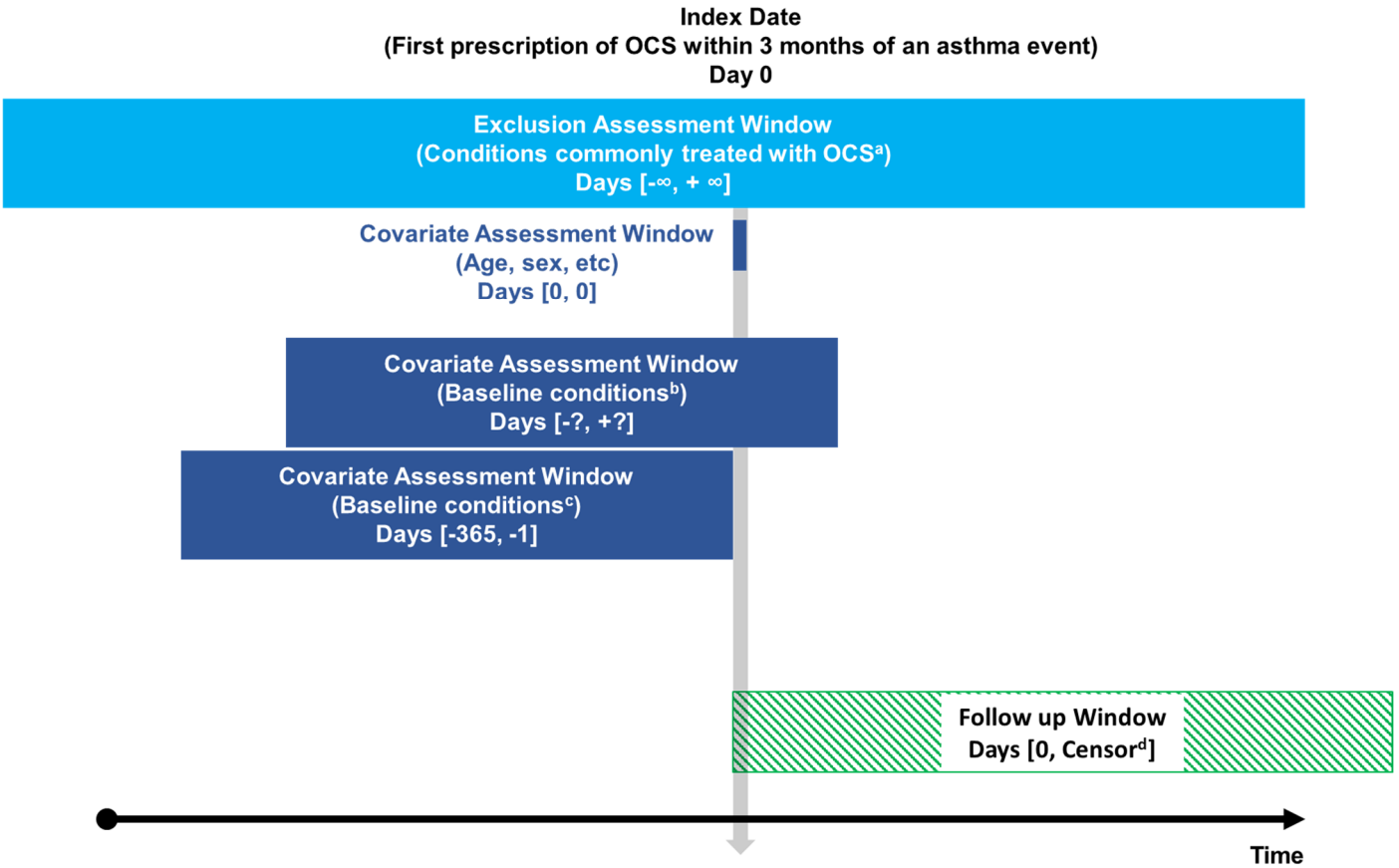


Y = Yes
N = No
U = Unknown

Inclusion and exclusion criteria will be used to define the patient population. Patients index date will be determined as their first OCS prescription with a concurrent (+/- 3 month i.e. 6-month interval) asthma event (Figure 2). Patients will be categorised according to their OCS patterns as defined previously (Table 1) and by demographic, clinical, and therapy indicators indicated below. Baseline patient characteristics to be described as part of Objective 1 include:

- patient characteristics described prior to index date
- length of patient record prior and after index date
- age of onset of asthma (age at first asthma diagnosis ever)
- time from first asthma diagnosis date to index date
- ICS and SABA use by OCS patterns and OCS patterns by ICS and SABA use
- patient's treatment by GINA (2019) treatment step prior to index date

Figure 2 - Study Design



a. Ankylosing spondylitis, Sjogren's syndrome, Systemic lupus erythematosus, Temporal arteritis, Ulcerative colitis, Psoriatic arthritis, Multiple sclerosis, Polymyalgia rheumatica, Crohn's disease, Cancer of respiratory system
b. Baseline conditions included e.g. most recent Height & Body Mass Index etc
c. Asthma Severity (GINA [2019] treatment step), BEC, Lung Function
d. Censored due to patient receiving a maintenance OCS prescription, leaving the database (de-registration or death), last collection date, or first AE event

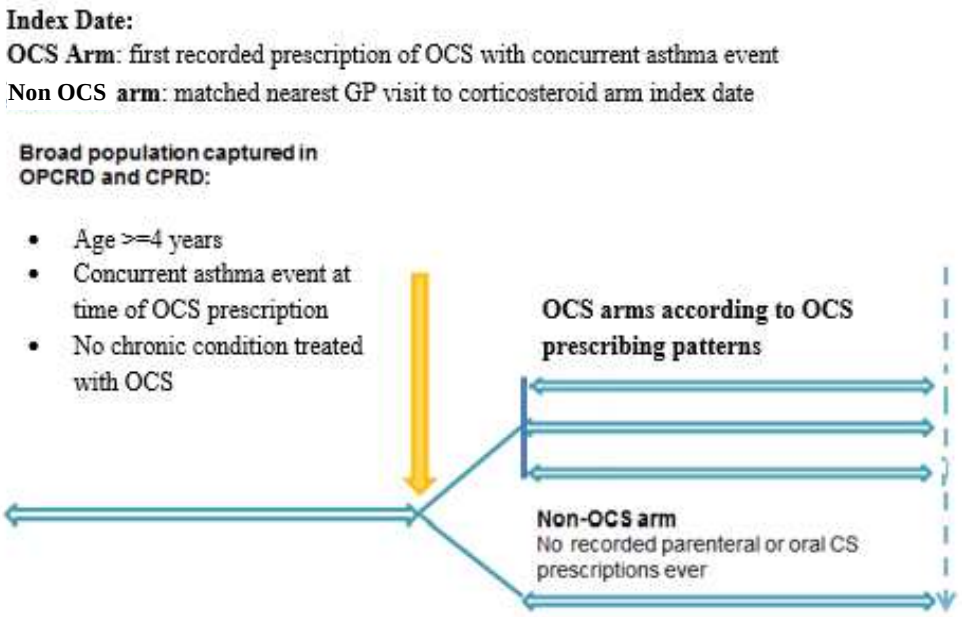
OCS = Oral Corticosteroid
BEC = Blood Eosinophil Count

Objective 2: To assess the association between different patterns of intermittent OCS use and OCS-related adverse outcomes in patients with asthma

A matched historical cohort study will be performed among patients selected from two anonymised, real-life databases containing patient's electronic medical records extracted from general practices in the United Kingdom (UK). The duration of the study will be from the time of the patient's first OCS with concurrent asthma event until the end-of-records. The study will

compare patients exposed to intermittent oral corticosteroids (OCS arm) and patients with asthma without any exposure to oral corticosteroids (non-OCS arm) (figure 3).

Figure 3 – Objective 2 Study design



The index date for the OCS arm will be the first recorded prescription of an OCS corticosteroid, while that of the non-OCS arm will be the nearest GP visit to the index date for the matched OCS arm patient. Patients within the two arms will be matched on gender

Primary outcome will be a diagnostic Read code for the following conditions: type 2 diabetes mellitus, osteoporosis/osteoporotic fractures, hypertension, glaucoma, sleep apnoea, weight gain[**] and depression/anxiety, pneumonia, cataracts, sleep disorders, cardiovascular disease, chronic kidney disease, dyslipidaemia and peptic ulcer disease, and in the adolescent population we will look for growth suppression and behavioural disorders.

Post hoc analysis will be undertaken to describe the rapidity of AE following OCS index.

Sample Size Estimations:

Diabetes: approximately 950 events will be needed to detect a 34% risk increase of diabetes onset for OCS patients,[31] assuming a two-sided alpha level of 0.05, power of 90%, ratio of cases to controls 1:3 and a correlation to other covariates of 0.3. With a baseline cumulative incidence

[**] Weight gain - Defined as: Increase in Body Mass Index (BMI)h by at least 1 kg/m2 compared to index date

of diabetes of 4%, this would mean following up approximately 4,800 patients over a period of 5 years or 12,000 patients over 2 years.

Osteoporosis/fracture risk: approximately 1000 events will be needed to detect a 33% risk increase of fracture at any site for OCS patients,[32] assuming a two-sided alpha level of 0.05, power of 90%, ratio of cases to controls 1:3 and a correlation to other covariates of 0.3. With a baseline cumulative incidence of osteoporosis of 1.6%, this would mean following up approximately 12,500 patients over a period of 5 years or 31,000 patients over 2 years.

Pneumonia: approximately 140 events will be needed to detect a 2.17-fold increase in pneumonia risk for OCS patients[33] assuming a two-sided alpha level of 0.05, power of 90%, ratio of cases to controls 1:3 and a correlation to other covariates of 0.3. With a baseline cumulative incidence of pneumonia of 0.45%, this would mean following up approximately 6,000 patients over a period of 5 years or 15,000 patients over 2 years.

A matched historical cohort study will be performed with an assessment of potential confounders during a baseline period prior to the index date. To address potential differences between treatment arms, patients will be matched initially on gender, and the index date. Other potential confounders (listed in 4.1.1) will be identified during the model building, using potential bias assessments of covariates, together with expert input.

For each risk cohort, patients are excluded if they had a record of the condition of interest before the index date.

Objective 3: To describe the impact of different patterns of intermittent OCS use on the frequency of healthcare resource utilisation in patients with asthma.

CPRD HES linked data will be used to describe hospital admissions, A&E attendances, and Outpatient visits

All HRU events and asthma specific events will be described for eight HRU categories described further below. These will be described for each of the prescribing pattern categories.

1. Physician office visits, categorized as 0, 1-4, 5-8, 9-12, 12-24, ≥25:
    a. General Practitioner (GP) consultations, all-cause
    b. Respiratory-related GP consultations
2. Outpatient visits (CPRD-HES only):
    a. Referrals to specialist, all-cause
    b. Referrals for asthma or other lower respiratory conditions

3. A&E attendances (CPRD-HES only):
    a. All-cause,
    b. Respiratory-related[††]
4. Hospital attendances, number of spells, *including day cases*:
    a. All-cause
    b. Asthma (ICD-10 J45/J46) as primary diagnosis
    c. Asthma (ICD-10 J45/J46) at any diagnostic position
    d. Respiratory conditions (ICD-10 J00-J99) as primary diagnosis
5. Hospital attendances, number of spells, *excluding day cases*:
    a. All-cause
    b. Asthma (ICD-10 J45/J46) as primary diagnosis
    c. Asthma (ICD-10 J45/J46) at any diagnostic position
    d. Respiratory conditions (ICD-10 J00-J99) as primary diagnosis
6. Hospital attendance, length of stay, *overall:* cumulative number of days per patient (including values of zero for patients not admitted to hospital)
    a. All-cause
    b. Asthma (ICD-10 J45/J46) as primary diagnosis
    c. Asthma (ICD-10 J45/J46) at any diagnostic position
    d. Respiratory conditions (ICD-10 J00-J99) as primary diagnosis
7. Hospital attendances, length of stay, *≥1 overnight*: cumulative number of days per patient, only reported for patients who remained overnight
    a. All-cause
    b. Asthma (ICD-10 J45/J46) as primary diagnosis
    c. Asthma (ICD-10 J45/J46) at any diagnostic position
    d. Respiratory conditions (ICD-10 J00-J99) as primary diagnosis
8. Day cases, number of spells (discharge date = admission date):
    a. All-cause
    b. Asthma (ICD-10 J45/J46) as primary diagnosis
    c. Asthma (ICD-10 J45/J46) at any diagnostic position
    d. Respiratory conditions (ICD-10 J00-J99) as primary diagnosis

Objective 4: To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up.

The unadjusted incidence rate of each adverse outcome in the OCs categories (250-499mg, 500-999mg, or =>1g) and non-OCS arms, as cases per 100 patient-years of follow-up (100 pt-yr), will be compared using the incidence rate difference and the incidence rate ratio (IRR) with 95% CIs. Each patient will be followed until the first occurrence of the outcome of interest and will be censored at death or the end of available records.

[††] HES variables DIAG2 = 25 (Respiratory conditions) or DIAG = 'AST%' or DIAG2 = 'J4%'

3.4 Study Population

The most recent extraction of EMR data from OPCRD and CPRD with linked HES data (HES data is currently upto March 2019) general practices for patients diagnosed with asthma, with no asthma resolved code to the latest available data.

The index date will be the patients first prescription of OCS within 3 months of an asthma related event (medication, asthma consultation and/or asthma diagnosis). Patients will be followed until the end of their EMR or their first prescription of a maintenance OCS. A 3-month window around the initial OCS date was included to help ensure that the OCS prescription related to an asthma clinical event.

3.5 Inclusion Criteria

The index date (ID) will be defined as the first OCS prescription for patients aged 4 or over within the study period with evidence of asthma (medication, asthma consultation and/or asthma diagnosis) in a 3-month window (either before or after the OCS prescription). Patients will also require at least 12 months baseline data (prior to index date) (Figure 2).

3.6 Exclusion Criteria

Asthma patients will be excluded if they have a chronic condition that is commonly treated with Oral Corticosteroids (i.e. ankylosing spondylitis, Sjogren's syndrome, systemic lupus erythematosus, temporal arteritis, ulcerative colitis, psoriatic arthritis, multiple sclerosis, polymyalgia rheumatica, Crohn's disease, cancer of respiratory system) recorded in at any time in the database.

Patients with a chronic AE outcome prior to the index date will be excluded from the analysis. This will ensure that the first chronic condition is the post index date incident event.

Patients in receipt of maintenance therapy will be excluded from the analysis as per the OPRI OCS algorithm.

3.7 Participant Follow-up

Data will be right censored at the end of data availability

4. VARIABLES AND EPIDEMIOLOGICAL MEASUREMENTS

4.1 Exposures

Exposure will be defined as a prescription of oral corticosteroids, which is prescribed for the treatment of a condition of interest (medication, asthma consultation and/or asthma diagnosis) during the calendar year of analysis.

The systemic corticosteroids contributing to OCS exposure in this study are shown in Table 2. Doses will be converted into prednisolone equivalents using the defined daily dose (DDD) obtained from the ATC/DDD classification system.[34]

Table 2 - Oral corticosteroid drugs

Drug name	Prednisolone equivalent conversion factor	ATC code systemic use	DDD
Betamethasone	6.67	H02AB01	1.5
Cortisone	0.27	H02AB10	37.5
Deflazacort	0.67	H02AB13	15
Dexamethasone	6.67	H02AB02	1.5
Hydrocortisone	0.33	H02AB09	30
Methylprednisolone	1.33	H02AB04	7.5
Prednisolone	1.0	H02AB06	10
Prednisone	1.0	H02AB07	10
Triamcinolone	1.33	H02AB08	7.5

OCS utilisation will be classified into periods of distinctive utilisation patterns. OCS utilisation patterns based on the spacing of OCS bursts until an event date will be used to classify OCS patterns. These patterns described previously (table 1) are:

a) One off – patients with only one OCS prescription,

b) Sporadic – prescriptions with gaps 365 days or over,

c) Infrequent – prescription with gaps of between 182 – 365 days,

d) Moderately infrequent - prescription with gaps of between 90 and 182 days,

e) Frequent – prescription gaps of less than 90 days and

f) Mixed – Patients with a mixture of the patters listed above.

Feasibility analysis described have already described the OCS patterns within the OPCRD data (1.4). The patterns for analysis in this study will include:

Patients that received a single OCS prescription,

Patients that received frequent or frequent and other mixed prescribing patterns

Patients that received sporadic or sporadic including other prescribing patterns

Sensitivity analysis will be included in these analyses following expert input from the steering committee.

4.1.1 Covariates/potential confounders add into analysis

Other covariates/potential confounders to be investigated include but not limited to:

- Baseline demographic variables
- Asthma severity (GINA treatment (2020))
- Inhaled corticosteroid use

4.2 Outcomes

Objective 1: To classify intermittent OCS prescriptions for patients with asthma and to describe longitudinal patterns of intermittent (acute) OCS use by GINA step, and ICS and SABA use.

Patients in receipt of maintenance therapy will be excluded from this analysis, baseline patient characteristics to be described as part of Objective 1 include:

- patient characteristics (age, gender, BMI, asthma control RCP3, blood eosinophil count, lung function) described prior to index date
- length of patient record prior and after index date
- age of onset of asthma (age at first asthma diagnosis ever)
- time from first asthma diagnosis date to index date
- ICS and SABA use prior to index date
- patient's treatment by GINA (2019) treatment step prior to index date

Objective 2: To assess the association between different patterns of intermittent OCS use and OCS-related adverse outcomes in patients with asthma

Patients in receipt of maintenance therapy will be excluded from this analysis. For each corticosteroid-related conditions, a multivariable Cox proportional hazard model will be fitted for each of the intermittent OCS patterns.[35] Conditional regression will be used to compare OCS use with non-OCS use in the matched populations. Regular Cox regression will be used to assess the hazard ratios of exposure in the OCS-arm only, either as continuous (dose/year) or categorical variables. Time to event will be defined as the time between index date and the onset of an AE. Patients without an AE will be censored at the end of follow-up.

Each analysis will be adjusted for the variables identified as confounders in the post-matching baseline analysis (section 4.1.1). Since it can be expected that variables can have similar associations with exposure and/or outcome, we will assess their bias conditional on the variables already in the model. Starting with a model containing the exposure measure and the variables that were forced into the model, all available covariates will be assessed on their bias potential (the relative change in coefficient they cause by being added to the model). The variable with the highest bias potential of at least 2% will be added to the model. Then, this process is repeated until either no more candidate confounders are available, or all available covariates show a bias potential of less than 2%.

Different time-dependent treatment measures (SABA use, ICS, and other maintenance use to determine GINA step) will be explored as covariates, as have been applied in previous studies: cumulative dose (g) and average daily exposure (mg/day).

A patient's cumulative dose will be calculated at as the sum of all prednisolone, or equivalent, doses (g) prescribed from index date up until the outcome event. In case of time-varying exposure, this will be assessed at the occurrence of each new prescription. In case of assessment at the end of follow-up, this will be assessed at the moment of the onset of the condition of interest, or the end of follow-up. Average daily exposure will be calculated by dividing the cumulative OCS dose received by a patient, by the time since index date.

Primary Outcome Variables

Onset will only be examined in the group of patients without a recorded clinician diagnosed condition prior to the index date.

1. **Type 2 diabetes mellitus onset**

Defined as:

i. Diagnosis of type 2 diabetes mellitus (Read code post index date) AND/OR

ii. Antidiabetic medication prescriptions in outcome period AND/OR

iii. HbA1c $\geq$ 6.5% in outcome period (Read code post index date)

2. Osteoporosis/osteoporotic fracture onset

Defined as:

i. Osteoporosis diagnostic code in outcome period (Read codes) AND/OR

ii. Osteoporotic fractures (hip, wrist or spinal fracture types only will be considered). A recurring fracture of the same site within 8 weeks of the previous fracture date will be counted as the same fracture. However, the patient will still be at risk of a fracture at a different site any time after the date of previous fracture

3. Hypertension onset

Defined as: Hypertension diagnostic code in outcome period (Read codes)

4. Glaucoma onset

Defined as:

i. Glaucoma diagnostic code in outcome period (Read codes) AND/OR

ii. Treatment for Glaucoma in the outcome period (section 4.1.7, Product/Read codes)

5. Sleep apnoea onset

Defined as:

i. Sleep apnoea diagnostic code in outcome period (Read codes) AND/OR

ii. Referral to sleep clinic in the outcome period AND

iii. Usage of a continuous positive airway pressure (CPAP) device

6. Weight gain

Defined as:

Increase in Body Mass Index (BMI) by at least 1 kg/m2 compared to index date in adults and more than 1% centile band.[36]

7. Depression/anxiety onset

Defined as:

i. Depression/anxiety diagnostic code in outcome period (Read codes) OR

ii. Depression/anxiety diagnostic code in outcome period AND antidepressant medications in the outcome period (section 4.1.7, Product/Read codes)

8. Pneumonia onset

Defined as:

Pneumonia diagnostic code in outcome period (Read codes). A recurring diagnosis of pneumonia within 4 weeks of prior diagnosis will be considered as the same event.

9. Cataracts onset

Defined as:

i. Cataract diagnostic code in outcome period (Read codes) AND/OR

ii. Cataract surgery (Yes/No)

10. Sleep disorders onset

Defined as:

i. Sleep disorder diagnostic code in outcome period (Read codes) AND/OR

ii. Sleep disorder diagnostic code and hypnotic medications in the outcome period (Read codes)

11. Cardiovascular disease onset

Defined as:

Cardiovascular disease diagnostic code for myocardial infarction, heart failure or stroke in outcome period (Read codes)

12. Renal impairment onset

Defined as:

i. Chronic kidney disease diagnostic code (only CKD stages 3a, 3b, 4 or 5 will be considered) AND/OR

ii. eGFR <60 mL/min/1.73m2 in outcome period (Read codes) AND/OR

iii. Dialysis code in the outcome period (Read codes) AND/OR

iv. Renal transplant code in the outcome period (Read codes)

13. Dyslipidaemia onset

Defined as:

i. Total cholesterol readings >6.5 mmol/l in outcome period AND/OR

ii. Low-density lipoprotein (LDL) readings >4 mmol/l in outcome period) AND/OR

iii. Triglycerides readings ≥2.3 mmol/L in outcome period AND/OR

iv. Diagnostic code for dyslipidaemia OR hyperlipidaemia OR hypercholesterolaemia OR hypertriglyceridaemia.

14. Peptic ulcer disease onset

Defined as:

Peptic ulcer disease diagnostic code (with endoscopy code for gastric ulcer and duodenal ulcer) in outcome period (Read codes)

15. Adolescent population – Behavioural disorders

Defined as:

Diagnostic code in outcome period to be determined by steering committee (Read codes)

16. Adolescent population - Growth suppression

Defined as:

Diagnostic code in outcome period (Read codes)

17. Mortality – Will be considered for inclusion at a later stage

Defined as:

Death certificate with AE (to be determined at a later stage) as the primary cause of death

Objective 3: To describe the impact of different patterns of intermittent OCS use on the frequency of healthcare resource utilisation in patients with asthma.

Patients in receipt of maintenance therapy will be excluded, outcomes are described as mean numbers ± standard deviation (SD), as median numbers with the interquartile range (IQR) and as categorical variables (0, 1, 2, 3, ≥4) for hospital admissions, A&E attendances and outpatient visits and specified below for other variables. Length of stay in hospital will be described as mean days ± standard deviation (SD), as median numbers with the interquartile range (IQR) and as categorical variables (0, 1, 2-7, 8-14, ≥14 days)

The HRU outcomes and associated costs will be calculated as annualised HRU and annualised costs for each of OCS pattern.

Annualised HRU will be calculated as:

$$\frac{\sum Count\ of\ HRU: index\ date\ till\ end\ of\ records}{Total\ months: index\ date\ till\ end\ of\ records}\ x\ 12$$

Annualised cost will be calculated as:

$$\frac{\sum Cost\ of\ HRU: index\ date\ till\ end\ of\ records}{Total\ months: index\ date\ till\ end\ of\ records}\ x\ 12$$

- Prices assigned to primary care consultation costs will be taken from the latest Personal Social Services Research Unit (PSSRU) document (https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2018/)
- Prices assigned to secondary care costs will be based on the national average hospital costs as found in PSSRU document
- Prices assigned to drugs will be taken from the Dictionary of Medicines and Devices browser (http://dmd.medicines.org.uk/). The electronic British National Formulary (eBNF) and the Medical Index of Medicinal Substances (MIMS) will be used to fill any gaps

HRU and associated costs will be assessed annually, and annual averages for the follow-up period will be calculated. We will estimate HRU-associated all-cause and cause-specific costs (2018 £) by multiplying HRU outcomes by the estimated unit costs associated with each HRU outcome from the Personal Social Services Research Unit, and the Dictionary of Medicines and Devices browser. Prescription costs will be obtained by multiplying cost by amount prescribed. Annualized HRU and healthcare costs will be reported for each OCS pattern.

Objective 4: To describe the AE for patients with an average annual OCS dose of 250-499mg, 500-999mg, or =>1g of OCS during the follow up.

The unadjusted incidence rate of each adverse outcome in the OCs categories (250-499mg, 500-999mg, or =>1g) and non-OCS arms, as cases per 100 patient-years of follow-up (100 pt-yr), will be compared using the incidence rate difference and the incidence rate ratio (IRR) with 95% CIs. Each patient will be followed until the first occurrence of the outcome of interest and will be censored at death or the end of available records.

4.3 Other Variables and Covariates

Table 2 - Variable measured at baseline

Fixed variables measured at baseline	
Age	Age in years on index date.
Gender	Female or Male
Height	Measurement in metres (m) on reading closest to index date, in adulthood
Body Mass Index (BMI)	Defined as the ratio of weight (kg) to squared height (m^2) closest to the index date. Categorised as: Adolescent (<18yo) [37] Calculated using UK reference population. Standardised BMI z-score based upon gender, weight, height and age Adult (18 and over) • Underweight <18.5 • Normal w eight 18.5 to <25 • Overweight 25 to <30 • Obese 30 and over
Age of Asthma Onset	This will be estimated from the available patient history using appropriate algorithms
Asthma severity	Patients categorised by GINA Treatment Steps
Asthma Control using RCP3 questionnaire	RCP questions recorded as part of an asthma review. Categorised as: • Controlled • Not controlled
Blood eosinophil count (BEC)	Highest blood eosinophils (10^9cells/L) in baseline year (or closest within 5 years of baseline). Categorised into groups of 10 x 10^9cells/L (**e.g.** <0.05, 0.05-<0.25, 0.25-<0.35, etc)
Lung function	Percent predicted PEFR at index date. Percent predicted FEV_1 at index date.
Total years of follow-up	Total follow-up time following index date
Number of SABA prescriptions (asthma control)	Total number of SABA prescriptions/inhalers/dose in baseline year (i.e. the year prior to the index date. Categorised **e.g. by 0, 1-2, 3-11, 12+, and 0,1-2,3+**

Number of ICS prescriptions	Total number of ICS prescriptions/inhalers/dose in baseline year (i.e. the year prior to the index date. Categorised by maximum dose **e.g. by 0 or 1+ etc**

Table 3 - Variable measured during follow up

Time-varying variables measured during follow-up	
SABA	Cumulative sum of SABA prescriptions up until the end of follow-up/year Cumulative dose of SABA (number of inhalers) up until end of follow-up/year
ICS	Cumulative sum of ICS prescriptions up until the end of follow-up as a proportion of total years of follow-up, **and/or** Cumulative dose of ICS (number of inhalers) up until end of follow-up as a proportion of total years of follow-up (Includes ICS-only inhalers and ICS-combination inhalers)
Other maintenance therapy to determine GINA step of treatment	Prescriptions up until the end of follow-up as a proportion of total years of follow up for LABA, LAMA, LTRA, anti-IL-5, anti-IgE and anti-IL-13 medications (Long-acting beta-agonists (LABA), long acting muscarinic antagonist (LAMA), Leukotrine receptor antagonist (LTRA))

4.3.1 Missing Data

Imputation of Prescription Strength and Dose

Missing value	Rule(s)
Date (days & months)	- Impute 15th of the month for missing days - Impute July 1st for missing days and months
Strength from generic active ingredient read codes	- Affects < 1% observations - Impute strength of branded/generic drug of the same active ingredient (by Read code) that is most frequently prescribed
Invalid quantity (number of units prescribed)	- Up to 35% invalid observations. Mostly quantity = 0 1. Impute most common strength of the same drug (by strength & Read code) for the patient 2. Impute most common quantity of drug of the same strength (by strength & Read code) prescribed for the OCS-related condition 3. Impute based on clinical input

4.3.2 Strengths and Limitations

It is worth noting that this analysis aims to include patients that are definite intermittent OCS users and therefore may exclude some patients that are potentially intermittent OCS patients. This a strength of the study, since specificity of exposure is more important than sensitivity in studies aimed at evaluating safety.

This study will use all eligible patients in two large real-world databases. The real-life design of this study provides high generalisability of the results to primary care patients managed in actual primary care practice. Additionally, the long observation period is a strength of the OPCRD and CPRD data for longitudinal studies.

This analysis will therefore likely be based on intermittent patients receiving a lower dose of OCS than those that are possible intermittent OCS patients, these results will therefore be conservative.

Exposure to OCS is estimated based on the number of prescriptions over time, which does not guarantee correct administration of OCS doses as prescribed.

Some of the study patients might have been exposed to systemic steroids outside the scope of the available medical record information, administered within a secondary care setting which isn't subsequently recorded on the patient's primary care EMR. Patients also move between GP practices which often makes their prior records inaccessible.

Using the first AE will underestimate the results as censoring patients after the onset of any outcome will exclude recurrent events.

Analysis of OPCRD does not have a link to secondary care and emergency department data, therefore, exposure to OCS prescribed in hospital cannot be considered. However, we know from our previous work that the mean asthma-related hospitalisation rate is 0.02 per year, so it is unlikely that this will relevantly influence the results; some hospital admission exacerbation records may not be recorded in the primary care records.

While a sophisticated algorithm based on all available data will be used, and this will be validated using expert opinion, it is possible that some of the OCS prescription may be misclassified.

The datasets represent information collected for clinical and routine use rather than specifically for research purposes. The validity and completeness of individual patient records cannot be assessed.

This analysis may have residual confounding due to factors that were not considered.

5. STUDY CONDUCT AND REGULATORY DETAILS

5.1 Data Management

CPRD data are delivered by AZ through their license. Database construction and analyses of data will be performed by OPRI.

5.2 Study Conduct

Analyses will be performed by the Observational & Pragmatic Research Institute.

A steering committee of respiratory research experts will be established to advise on the study.

Suggested members of the steering committee are:

- Josef Smolen (Internal Medicine, Medical University of Vienna, Austria)
- Andrew Menzies-Gow (Royal Brompton & Harefield NHS Foundation Trust, UK)
- David Jackson (Faculty of Medicine, National Heart & Lung Institute, Imperial College London, UK)
- Anaud Bourdin (Centre Hospitalier Universitaire de Montpellier, France)
- Prof David Price (OPRI)
- Dr Trung N. Tran (AZ)

5.2.1 Study Flow Chart and Plan

TIMELINE PROJECTION TO STUDY COMPLETION		
Department/Activity	**Estimated Delivery Time**	**Contracted Timeline**
Draft Protocol to AZ (Objective 1)		03.08.2020
Final Protocol to ADEPT & ISAAC (Objective 1)	+2 weeks (2 week)	17.08.2020
Dataset Created: OPCRD (Objective 1,2 & 4)	+2 week (4 weeks)	31.08.2020
Analysis OPCRD (Objective 1,2 & 4)	+5 week (9 weeks)	05.10.2020
Potential Arrival of CPRD data	(9 weeks)	05.10.2020
Dataset Created: CPRD (Objective 1-4)	+3 weeks (12 weeks)	26.10.2020
Analysis CPRD (Objective 1-4)	+5 weeks (17 weeks)	30.11.2020
Final Study Report Delivery	+8 weeks (25 weeks)	29.01.2021

5.2.2 Procedures

5.2.3 Quality Control

All code for dataset generation, dataset preparation and analyses will be reviewed by a second researcher. All data will be reviewed for correctness and completeness, and the data will be cleaned appropriately. All code lists used for this study will be reviewed by a clinician or a pharmacologist.

5.3 Protection of Human Subjects

The Observational Study will be performed in accordance with ethical principles that are consistent with the Declaration of Helsinki, ICH GCPs, GPP and the applicable legislation on Non-Interventional Studies and/or Observational Studies.

The Investigator will perform the Observational Study in accordance with the regulations and guidelines governing medical practice and ethics in the country of the Observational Study and in accordance with currently acceptable techniques and know-how.

5.4 Communication Plan

5.4.1 Publication Plan

The results will be presented in at least in one national/international conference and a manuscript will be submitted to a journal.

5.4.2 Compliance with Study Registration and Results Posting Requirements

The study will be registered at ENCePP (http://www.encepp.eu/).

5.4.3 Compliance with Financial Disclosure Requirements

Any information that may be seen as a conflict of interest in terms of compensation or financial interests will be disclosed for each investigator.

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7. APPENDICES

8.1 BTS Treatment Steps

BTS steps are defined as 1=no regular preventer, 2=lowest ICS dose appropriate for age (or LTRA alone if <5 years), 3=add LABA (add LTRA if <5 years), 4=increase ICS dose to next level (medium in adults, low dose in children), may add in other therapy (adults: LTRA, theophylline, LAMA; children: LTRA), 5=increase ICS dose (high in adults, medium in children), add fourth drug (adults: LTRA, theophylline, beta agonist tablet, LAMA; children: theophylline), 6=same ICS dose and continuous or frequent use of oral steroids

8.2 GINA Treatment Steps

<table>
<tr><th></th><th>Step 1</th><th>Step 2</th><th>Step 3</th><th>Step 4</th><th>Step 5</th></tr>
<tr><td>PREFERRED CONTROLLER CHOICE</td><td>As needed Low dose ICS-formoterol</td><td>Daily low dose ICS or as needed low dose ICS-formoterol</td><td>Low dose ICS/LABA</td><td>Med dose ICS/LABA</td><td>High dose ICS/LABA
Refer for add-on treatment e.g. tiotropium, anti-IgE, anti- IL5/5R, anti-IL4R</td></tr>
<tr><td>Other controller options</td><td>Low dose ICS taken with SABA</td><td>Leukotriene receptor antagonist (LTRA) or low dose ICS taken with SABA</td><td>Med dose ICS
Low dose ICS+LTRA</td><td>High dose ICS, add-on tiotropium or add-on LTRA
(or + theoph)</td><td>Add low dose OCS but consider AEs</td></tr>
<tr><td>PREFERRED RELIEVER</td><td colspan="2">As needed low dose ICS-formoterol</td><td colspan="3">As needed low dose ICS-formoterol</td></tr>
<tr><td>Other Options</td><td colspan="5">As needed SABA</td></tr>
</table>

8.3 OCS Acute Dosing Instructions

dose_id	text_dose
422	15
1062	20D
1359	30D
2476	REDUCING
2494	SIX EVERY DAY
5796	SIX TO BE TAKEN DAILY
20098	6 TABLETS DAILY FOR 10 DAYS
20111	TAKE 4 DAILY FOR 5 DAYS
20117	USE 6 TABLETS DAILY FOR 5 DAYS
20118	6 ONCE DAILY30
20119	SIX TABS DAILY FOR 5 DAYS
20120	6tabs daily for 5 days
20123	TAKE FOUR TABLETS EACH MORNING (AS A SINGLE DOSE) FOR 3 DAYS.
20132	SIX TABLETS A DAY FOR 5 DAYS
20136	TAKE 8 TABLETS TOGETHER DAILY FOR 5 DAYS
20140	6 TABS IN THE MORNING FOR 5 DAYS
20147	FOUR TABLETS DAILY FOR FIVE DAYS
20148	TAKE 6 TABLETS ONCE A DAY FOR 5 DAYS
20161	TAKE EIGHT TABLETS A DAY FOR FIVE DAYS
20182	TAKE 8 DAILY FOR 7 DAYS
20196	4 a day for 3 days
20198	Take eight tablets in one dose for five days with food
20200	four tablets daily for three days
20205	6 DAILY FOR SEVEN DAYS
20206	6/DAY FOR 5 DAYS
20209	TAKE 6 A DAY FOR 7 DAYS
20213	six TABLETS DAILY FOR 3 DAYS
20215	6daily for 5 days
20216	Take six tablets daily for five days
20217	TAKE 6 DAILY FOR 3 DAYS
20220	8 daily for five days
20227	8 TABLETS FOR 5 DAYS
20228	TAKE 8 TABS DAILY FOR 5 DAYS
20229	4 DAILY FOR 1 WEEK
20231	TAKE 6 TABS DAILY FOR 5 DAYS
20237	eight Tabs Daily for 5 days This medicine can cause irritation of the stomach lining. Eating food before taking it will reduce this effect. If you experience severe indigestion symptoms contact your GP.
20239	take 4 daily for 3 days
20242	6 daily for 5 days only

20246	8 IN THE MORNING FOR ONE WEEK
20251	TAKE FOUR TABLETS EACH MORNING (AS A SINGLE DOSE) FOR 5 DAYS.
20257	3 TABLETS DAILY FOR 3 DAYS
20259	8D FOR 5D
20260	6 od for one week
20263	TAKE EIGHT DAILY FOR FIVE DAYS
20264	8 tabs altogether for 5 days
20265	8D
20269	TAKE 6 TABLETS FOR 5 DAYS
20274	6 TABLETS DAILY FOR 1 WEEK
20279	4 EVERY DAY FOR 5 DAYS
20283	take 6 tablets a day for 5 days
20284	6 TABS DAILY FOR 1 WEEK
20291	TAKE 8 TABLETS ONCE DAILY FOR 5 DAYS
20295	TAKE 6 PER DAY FOR 5 DAYS
20298	6 TABS ALTOGETHER EACH AM FOR 1 WEEK
20301	four tablets daily for 5 days
20312	8 tablets od for 5 days @NB -
20313	8 TABLETS EVERY DAY FOR 5 DAYS
20318	8 TABS IN THE MORNING FOR 5 DAYS
20319	8 TABLETS ONCE DAILY FOR 7 DAYS
20325	8 together once daily for 5 days
20327	8 ONCE DAILY FOR 1 WEEK
22094	6 EVERY DAY FOR 5 DAYS
22270	30MG EVERY DAY
22271	REDUCING DOSE
22451	eight tablets daily for five days
22458	6 per day for 5 days
22723	8 EVERY DAY FOR 5 DAYS
22724	6 A DAY FOR 5 DAYS
22825	8 TABLETS DAILY FOR 5 DAYS
23386	30mg od
23557	6 daily for 5 days
24893	4 DAILY FOR 5 DAYS
25649	8 od for 5 days
25651	6 EVERY DAY FOR 3 DAYS
25672	4 DAILY FOR 3 DAYS
25681	6 od for 5 days
25682	8 ONCE DAILY FOR 5 DAYS
25842	6 DAILY FOR 3 DAYS
26291	40MG DAILY FOR 5 DAYS

27993	30 MG DAILY FOR 5 DAYS
27997	30 MG
28161	8 TABLETS ONCE DAILY FOR 5 DAYS
28162	30 MG (6 TABS) ONCE DAILY FOR 5 DAYS
28550	6 ONCE DAILY FOR 1 WEEK
28990	40 MG
29865	30MGS DAILY
30187	5 daily for 6 days
30499	4 TABLETS DAILY FOR 5 DAYS
30657	SIX TABLETS DAILY FOR FIVE DAYS
30845	6 TABLETS DAILY FOR 3 DAYS
31102	6 tablets daily for 5 days
31363	eight tablets daily for 5 days
32705	5 daily for 5 days
33182	take six daily for 5 days
33882	6 tablets every day for 5 days
34331	8 DAILY FOR 1 WEEK
34431	8 DAILY FOR 5 DAYS
34434	6 TABLETS ONCE A DAY FOR 5 DAYS
34674	take 6 daily for 5 days
35425	REDUCING REGIME
39304	3 DAILY FOR 4 DAYS
40529	8 TABLETS A DAY FOR 5 DAYS
40604	6 EVERY DAY FOR 1 WEEK
41142	take 8 tablets daily for 5 days
41190	6 TABLETS A DAY FOR 5 DAYS
41274	6 daily for 1 week
41608	60D
41669	8 A DAY FOR 5 DAYS
41714	REDUCING DOSE AS DIRECTED
42345	SIX A DAY FOR 5 DAYS
43629	4 a day for 5 days
44189	SIX TABLETS DAILY FOR 5 DAYS
46636	20mg od
46928	6 TABS DAILY FOR 5 DAYS
47105	REDUCING COURSE AS DIRECTED
48505	40 mg daily
48627	TAKE 8 IN THE MORNING FOR 5 DAYS
48869	30 MG DAILY
49200	40 MG ONCE DAILY FOR 5 DAYS
49470	40 MG ONCE DAILY

49562	6 a day for 7 days
49735	30 MG ONCE DAILY FOR 5 DAYS
49777	20 mg daily
51078	20 MG
51100	15 mg daily
51224	8 tabs daily for 5 days
51835	TAKE 6 IN THE MORNING FOR 5 DAYS
52325	6 ONCE DAILY FOR 5 DAYS
52511	60 MG DAILY
52946	8 DAILY FOR 7 DAYS
53177	4 AS DIRECTED
53449	6 DAILY FOR 5 DAYS THEN 3 DAILY FOR 5 DAYS
53770	25 mg daily
53855	EIGHT DAILY FOR FIVE DAYS
54046	8 tabs once daily for 5 days
54930	6 daily for 7 days
55516	20 MG ONCE DAILY
55609	6 ONCE DAILY FOR 3 DAYS
55870	six daily for five days
56199	6 TABLETS ONCE DAILY FOR 5 DAYS
56494	6 A DAY FOR 3 DAYS
57717	6 DAILY FOR 10 DAYS
58165	4 DAILY FOR 7 DAYS
58233	6 DAILY FOR 5 DAYS THEN STOP
58607	REDUCE AS DIRECTED
59820	3 ONCE DAILY FOR 5 DAYS
59892	6 DAILY FOR 2 WEEKS
60299	30 MG IN THE MORNING
61576	3 DAILY FOR 5 DAYS
61786	8 DAILY FOR 3 DAYS
62265	6 DAILY FOR 4 DAYS
62782	6 TABLETS FOR 5 DAYS
63743	6 TABS ONCE DAILY FOR 5 DAYS
64195	take 6 a day for 5 days
64196	40MG DAILY
65831	6 TABS DAILY FOR 7 DAYS
66397	take 6 tablets daily for 5 days
67041	2 DAILY FOR 3 DAYS
67553	4 daily for 5/7
67902	8 a day for 7 days
68067	6 daily for 5days

68368	six daily for one week
68621	3 DAILY FOR 3 DAYS
69045	30MG DAILY
72443	654321
72851	Take six daily for five days
73922	REDUCING COURSE
75245	4 ONCE DAILY FOR 5 DAYS
75642	6 DAILY FOR 5 DAYS.
76282	6 DAILY 5 DAYS
76993	TAKE 8 A DAY FOR 5 DAYS
77505	6 DAILY FOR A WEEK
77506	8 DAILY FOR 10 DAYS
78674	6 TABLETS IN THE MORNING FOR 5 DAYS
78676	Take 8 daily for 5 days
79335	REDUCING AS DIRECTED
79629	30 MG DAILY FOR 3 DAYS
81076	15 MG ONCE DAILY
81089	4 ONCE DAILY FOR 3 DAYS
81223	20 mg daily for 3 days
81448	6 ONCE DAILY FOR 7 DAYS
85299	8 TABLET(S) DAILY FOR 5 DAYS
85912	6 TABS DAILY FOR 3 DAYS
87397	8 TABS EVERY DAY FOR 5 DAYS
88697	6 daily for five days
89592	30MG DAILY FOR 5 DAYS
91933	30 MG ONCE DAILY
92254	30 MG FOR 5 DAYS
92278	6 IN THE MORNING FOR 5 DAYS
92791	30 MG ONCE DAILY FOR 3 DAYS
93137	8 ONCE DAILY FOR 7 DAYS
93508	30 MG IN THE MORNING FOR 5 DAYS
95254	8 IN THE MORNING FOR 5 DAYS
100712	30 mg od
101139	20MG DAILY
102101	6 tablets daily after food
102167	SIX DAILY FOR 5 DAYS
102168	EIGHT DAILY FOR 5 DAYS
102494	6 TABS A DAY FOR 5 DAYS
103958	4 DAILY FOR 4 DAYS
106889	4 TABS DAILY FOR 3 DAYS
107192	6 tablets od for 5 days

107677	6 IN THE MORNING FOR 7 DAYS
107898	2 DAILY FOR 5 DAYS
111315	8 daily 5 days
112185	SIX A DAY FOR FIVE DAYS
114254	6,5,4,3,2,1
115664	4 TABS DAILY FOR 5 DAYS
115678	4 TABLETS DAILY FOR 3 DAYS
116332	take 6 once daily for 5 days
118251	take 6 daily for 7 days
118425	6 tabs od for 5 days
118610	TAKE 8 TABLETS DAILY FOR 7 DAYS
118620	TAKE SIX TABLETS DAILY FOR 5 DAYS
119070	TAKE 6 TABLETS ONCE DAILY FOR 5 DAYS
123159	6 daily for 6 days
123747	30mg
125675	54321
125757	87654321
140941	REDUCING DOSE AS ADVISED
142922	20MG
148005	15MG DAILY
161250	40 MG DAILY (8 TABLETS)
161689	30 MG DAILY (6 TABLETS)
163781	25 MG ONCE DAILY
171953	40 mgs daily
172482	30 MGS DAILY AS ONE DOSE PC
172484	40 MGS DAILY AS ONE DOSE
172488	30 MGS DAILY
172961	ASD REDUCING DOSE
175517	6 OD FOR 1 WEEK
176279	8 IN THE MORNING FOR 7 DAYS
176334	40 mg daily for 5 days
176551	6 ONCE DAILY FOR 2 WEEKS
176727	2 DAILY FOR SIX WEEKS AND THEN 1 DAILY
176898	20 MGS DAILY
181293	6 TABLET ONCE DAILY FOR 5 DAYS
181548	30 mg/day
182981	6 /day for 1 week
189041	40mg od
207464	TAKE SIX TABLETS DAILY FOR 5 DAYS . TAKE AFTER FOOD
207470	TAKE SIX TABLETS DAILY FOR 5 DAYS THEN REDUCE BY ONE EACH DAY. TAKE AF
207483	TAKE SIX DAILY FOR 5 DAYS AND THEN REDUCE BY ONE EACH DAY. TAKE AFTER

229892	SIX DAILY FOR 10 DAYS
244368	6 IN THE MORNING FOR 1 WEEK
270105	TAKE 8 TABLETS ONCE A DAY FOR 5 DAYS
293572	8 TABLETS (40 MG) ONCE DAILY FOR 5 DAYS
294428	20 MG DAILY FOR 5 DAYS
294487	30 mg daily for 7 days
298969	SIX DAILY FOR SEVEN DAYS
299702	six tablets daily for seven days
303431	30 mg om
310363	6 FOR 5 DAYS
319222	20 mg od
320081	20MG EVERY DAY
332415	6 ONCE DAILY FOR 10 DAYS
333763	8 TABS ONCE DAILY FOR 7 DAYS
341052	8 DAILY FOR 2 DAYS AND THEN 7 DAILY FOR 2 DAYS AND CONTINUE TO REDUCE DOSE BY ONE TABLET EVERY OTHER DAY
341253	6 /day for 5 days
344252	8 TABS ONCE DAILY REDUCING AS DIRECTED BY 5 MG (1 TAB) PER WEEK
344770	30 MG ONCE DAILY FOR 7 DAYS
345080	40 MG OM
356760	8 TABLETS DAILY FOR 7 DAYS
387887	8 PER DAY FOR 5 DAYS
391280	40
393453	6 TABLETS DAILY FOR 5 DAYS THEN STOP
394406	AS DIRECTED REDUCING DOSE
402313	8 TABLETS ONCE A DAY FOR 5 DAYS
408137	40 MG PO ONCE DAILY FOR 4 DAYS
413664	30 MG ONCE DAILY WITH FOOD
415463	30 MG/DAILY
427676	6 daily for one week
430015	ON REDUCING DOSE
433858	REDUCE DOSE AS DIRECTED
435551	6 TABLETS DAILY FOR 7 DAYS
435894	TAKE 6 TABLETS DAILY FOR 7 DAYS
436065	6 TABLETS DAILY FOR FIVE DAYS
437363	2 DAILY FOR 5 DAYS THEN 1 DAILY
437952	6 TABS EVERY MORNING FOR 5 DAYS
448839	6 STAT REDUCE BY 1 DAILY
455847	8 /DAY FOR 5 DAYS
455965	TAKE 8/DAY FOR 5 DAYS
456127	6 /DAY FOR 5DAYS
471629	TAKE SIX A DAY FOR FIVE DAYS

480689	EIGHT DAILY FOR 7 DAYS
486771	40 mg od
487015	TAKE 6 TABLETS DAILY FOR 10 DAYS
492437	TAKE ONE DAILY AS DIRECTED
498626	REDUCING DOSE AS DISCUSSED
519390	8 TABLET DAILY FOR 5 DAYS
531388	8 TABLET ONCE DAILY FOR 5 DAYS
537677	30 mg od for 5 days
549330	4D
565974	8 TABS ONCE DAILY FOR 1 WEEK
688372	6 a day for three days use as directed
714377	1 daily reduce dosage when better
754620	6 daily for 5 days to keep a course at home
828600	TAKE EIGHT TABLETS DAILY FOR FIVE DAYS
841919	as per reducing dose
870038	8 TABS DAILY FOR 7 DAYS
887749	6 ONCE DAILY FOR SEVEN DAYS THEN 3 ONCE DAILY FOR SEVEN DAYS
891147	30 MG EVERY DAY
900884	6 EVERY DAY FOR 7 days
901164	2 Tabs Daily for 7 days
915958	6 ONCE DAILY FOR 1 WEEK;THAN REDUCE BY 1 PER DAY
958156	40MG EVERY DAY
973999	40 MGS ONCE DAILY
997332	SIX EVERY DAY FOR 5/7
997561	SIX EVERY DAY FOR 10/7
998508	SIX EVERY DAY FOR FIVE DAYS
1021203	TAKE 8 TABLETS DAILY FOR FIVE DAYS
1026028	TAKE 6 FOR 5 DAYS THEN STOP
1033003	REDUCING DOSE AS DIRECTED BY HOSPITAL
1043573	6 daily for 1wk
1065150	40 MG/DAILY
1082799	Take six daily for one week then take three daily for one week
1085894	8 TABLETS IN THE MORNING WITH FOOD FOR 5 DAYS
1100912	SIX AS DIRECTED
1137220	30 MG ONCE DAILY(6 TABS)
1188492	SIX DAILY FOR 7 DAYS
1212163	OVER 5 YEARS TAKE 6 DAILY FOR 3 DAYS
1228699	UNDER 5 YEARS TAKE 4 DAILY FOR 3 DAYS
1308303	80D
1365184	40 MG DAILY FOR 5 TO 7 DAYS
1365193	30 MG DAILY

1365316	40 MG DAILY
1365353	20 MG DAILY
1365665	50 MG DAILY
1370098	30mg daily for 7 days
1394786	TAKE 6 EVERY DAY FOR 7 DAYS IN EVENT OF EXACERBATION OF COPD
1401170	between 30-60mg daily
1413578	15MGS ONE DAY 10MGS EVERY OTHER DAY DIE
1424026	TAKE AS DIRECTED IN THE EVENT OF ACUTE EXACERBATION OF ASTHMA
1502904	adjust dosage according to instructions from your Doctor
1519076	6 OD FOR 7 DAYS
1587491	TAKE EIGHT DAILY FOR 7 DAYS
1604258	6 DAILY FOR 5 DAYS AND THEN STOP
1678391	TAKE 6 TABLETS DAILY FOR 7 DAYS. THIS IS AN EMERGENCY COURSE OF STEROI
1777794	TWO TABLETS DAILY FOR FIVE DAYS
1862607	6 DAILY FOR WEEK
1865672	40 mgs od
2043097	EIGHT TABS DAILY FOR 5 DAYS
2044794	two tablets daily for 5 days
2048015	TAKE EIGHT TABLETS EACH MORNING (AS A SINGLE DOSE) FOR 5 DAYS
2048622	TAKE SIX TABLETS EACH MORNING (AS A SINGLE DOSE) FOR 7 DAYS.
2112703	6 TABS A DAY FOR 5 DAYS THEN REDUCE BY ONE A DAY TILL FINISHED
2181245	7654321
2296897	6 TABS ONCE DAILY FOR 7 DAYS
2420709	6 TABLETS DAILY USUALLY IN THE MORNING FOR 7 DAYS
2638584	8 OD FOR 1 WEEK THEN REDUCE BY 1 EVERY OTHER DAY
2665007	8 OD FOR 1 WEEK THEN REDUCE BY 1 EVERY OTHER DAY (TO HELP BREATHING).
2665487	8 OD FOR 1 WEEK THEN REDUCE BY 1 EVERY OTHER DAY (TO HELP BREATHING)
2835063	6 od for 1 week (RESCUE PACK FOR CHEST)
2835649	6 od for 1 week (RESCUE PACK)
2968652	30MG FOR 7 DAYS
3129995	6 ONCE DAILY 5 DAYS, 3 ONCE DAILY 5 DAYS
3133209	6 daily 5 days, 3 daily 5 days
3248057	8 TABLETS ONCE A DAY (AFTER BREAKFAST) FOR 5 DAYS
3248154	8 DAILY IN THE MORNING FOR 5 DAYS (AFTER FOOD)
3248744	6 TABLETS ONCE A DAY (AFTER BREAKFAST) FOR 5 DAYS
3248915	6 TABLETS ONCE A DAY (AFTER BREAKFAST) FOR 14 DAYS
3248972	6 TABLETS ONCE A DAY (AFTER BREAKFAST) FOR 10 DAYS
3253085	6 TABLETS ONCE A DAY (AFTER BREAKFAST) FOR 10-14 DAYS
3253186	eight Tabs Daily for 5 days This medicine can cause irritation of the
3289075	TAKE SIX TABLETS EACH MORNING (AS A SINGLE DOSE) FOR 3 DAYS.
3309756	6,5,4,3,2,1, AS DIRECTED

3381661	6 EVERY DAY 1/52
3553156	6,5,4,3,2,1 AS DIRECTED
4058519	6 wk1; 4 wk 2 2 w 3 Daily 6 tablets week 1
4190352	EIGHT AS DIRECTED
4214636	6 TABLETS DAILY FOR 4 DAYS AND 4 TABLETS ON FINAL DAY
4300461	8 TABLET ONCE DAILY FOR 5 DAYS -PRN COURSE
4352687	4 FOR 3 DAYS THEN 2 FOR 3 DAYS THEN 1
4354127	standby script 6 daily
4378104	6 /6/5/5/4/4/3/3/2/2/1/1/day
4398838	6 EVERY DAY 1/52 THEN 3 EVERY DAY 1/52
4518850	8 TABLETS DAILY FOR 7 DAYS AND THEN REDUCING REGIME AND TO STOP AT END OF 2 ND WEEK
4565628	TWO TABLETS DAILY FOR FIVE DAYS then 1 daily
4568184	6 X 5MG TAB DAILY 5 DAYS
4828894	TAKE SIX 5MG TABLETS EVERY DAY FOR 7 DAYS (EMERGENCY STEROIDS FOR SHOR
4896695	6 A DAY 1 WEEK THEN 3 A DAY 1 WEEK
4907454	take six daily 1/52 then 3 daily 1/52
4954297	8 TABLETS DAILY FOR 5 DAYS, THEN REDUCE BY ONE TABLET A DAY.
5063265	6 FOR 5/7,4 FOR 3/7, THEN 2 FOR 3/7 THEN 1
5069936	take six daily until asthma controlled for 2 days, then gradually reduce to the lowest dose at which symptoms are still controlled
5070376	4 FOR 5/7 THEN 2 FOR 5/7 THEN 1 FOR 5/7
5081038	as directed- reduce by 5 mgs every 4 days
5258282	8 EVERY MORNING FOR 7 DAYS THEN REDUCE AS DIRECTED
5259340	8,7,6,5,4,3,2,1
5358527	TAKE 8 A DAY FOR EXACERBATIONS
5359507	TAKE 6 A DAY FOR EXACERBATIONS
6974853	TAKE 8 TABLET(S) ONCE A DAY FOR 5 DAYS
6975069	TAKE 8 TABLET(S) ONCE A DAY FOR ONE WEEK THEN REDUCE BY ONE TABLET EACH DAY OVER SEVEN DAYS
6978056	TAKE SIX A DAY FOR 10 DAYS THEN REDUCE BY ONE DAILY UNTIL FINISHED COURSE.
6979384	reduce to 7 tablets one day , then six tablets , then five, then foure , then three, then two, then one tablet a day , then stop.
6984170	EIGHT REDUCING TO ONE EVERY MORNING AFTER FOOD
6984189	SIX REDUCING TO ONE
6985211	EIGHT EVERY MORNING REDUCING TO ONE EVERY MORNING AFTER FOOD
6989310	SIX REDUCING TO ONE EVERY MORNING AFTER FOOD
7010416	6 DAILY THEN REDUCE TO 5;4;3;2;1
7010890	2 TABLETS DAILY WITH FOOD FOR 3 DAYS THEN ONE TABLET DAILY UNTIL COURSE COMPLETED
7057477	5 DAILY FOR 2 DAYS 4 DAILY FOR 2 DAYS 3 DAILY FOR 2 DAYS 2 DAILY FOR 2 DAYS 1 DAILY FOR 2 DAYS AND STOP
7077500	6 A DAY FOR 4/7 THEN 4 A DAY FOR 4/7 THEN 2 EVERY DAY FOR 4/7 THE ONE
7098860	6 a day 7 days then reduce by one every 3 days
7098861	take 4 a day for 2 days then reduce by one daily

7099465	SIX DAILY FOR 5 DAYS THEN REDUCE BY ONE A DAY
7107642	8,7,6,5,4,3,2,1,
7122527	66554433
7134611	TAKE 8 A DAY FOR 5 DAYS THEN 6,4,2 THEN STOP
7135118	7.6.5.4.3..
7143328	SOLUBLE TABLETS 6 DAILY FOR 4 DAYS THEN REDUCE TO 3 DAILY
7143436	6 5 4 3 2 1.
7147449	8 DAILY TILL BETTER THEN 4 DAILY FOR SAME NO OF DAYS KEEP THE REST FOR A FURTHER ATTACK
7152705	8 daily till better then 4 daily for the same no of days
7155047	8,8,7,6,5,4,3,21 THEN STOP
7172754	TAKE 30MGS ONCE A DAY FOR 5 DAYS AND 15MGS A DAY FOR THE FOLLOWING 15 DAYS
7182773	6 DAILY TIMES 4 THEN 4 DAILY TIMES 4 THEN 2 DAILY
7184120	5;4;3;2 & 1 TABLETS TO BE TAKEN ON CONSECUTIVE DAYS
7184122	6;5;4;3;2;1 TABLETS ON CONSECUTIVE DAYS
7188810	DECREASING
7194097	6ODCCREDUCE
7194235	6ODREDUCING
7194632	6ODCC REDUC
7222881	reduce to 7 daily for 1 week then reduce by 1 tablet each week
7229471	8 TABLETS A DAY FOR 2 DAYS, 6 TABLETS FOR 2 DAYS , 4 ADAY FOR TWO DAYS
7231588	4 TABS DAILY FOR 7 DAYS THEN 2 DAILY FOR 2 DAYS THEN 1 DAILY FOR 2 DAYS THEN STOP
7231589	6 TABS DAILY FOR 7 DAYS THEN 4 DAILY FOR 4 DAYS THEN 2 DAILY FOR 4DAYS THEN STOP
7276080	TAKE 8 TABS STRAIGHT AWAY THEN REDUCE BY ONE TABLET EACH DAY TO STOP.
7286283	4 ONCE DAILY FOR 2 DAYS; 3 ONCE DAILY FOR 2 DAYS; 2 ONCE DAILY FOR 2 DAYS; 1 ONCE DAILY FOR 2 DAYS
7292220	6 TABS DAILY FOR 5 DAYS THEN REDUCE BY ONE TABLET(S) DAILY
7318532	40 MG ONCE DAILY FOR 5 D
7325439	6 a day; reduce by 1 each day
7328746	30 MG IN THE MORNING FOR 5 DAYS THEN REDUCE GRADUALLY
7328979	REDUCE BY 5 MG EV 2 DAYS UNTIL STOPPED
7443438	TAKE 4 TODAY THEN 3 2 AND 1
7490074	8 Tabs each morning for seven days
7503111	then 4 daily for 5 days

8.4 Asthma Read Codes

read_code	read_term
173A.	Exercise-induced asthma
H3120	Chronic asthmatic bronchitis
H33..	Asthma

H330.	(Hay fever with asthma) or (extrinsic asthma without status asthmaticus)
H3300	Extrinsic asthma without status asthmaticus
H3301	Extrinsic asthma with: [asthma attack] or [status asthmaticus]
H330z	Extrinsic asthma NOS
H331.	Intrinsic asthma
H3310	Intrinsic asthma without status asthmaticus
H3311	Intrinsic asthma with: [asthma attack] or [status asthmaticus]
H331z	Intrinsic asthma NOS
H332.	Mixed asthma
H334.	Brittle asthma
H335.	Chronic asthma with fixed airflow obstruction
H33z.	Asthma unspecified
H33z0	(Severe asthma attack) or (status asthmaticus NOS)
H33z1	Asthma attack
H33z2	Late-onset asthma
H33zz	Asthma NOS
H3B..	Asthma-chronic obstructive pulmonary disease overlap syndrome
Ua1AX	Brittle asthma
X101t	Childhood asthma
X101u	Late onset asthma
X101x	Allergic asthma
X101y	Extrinsic asthma with asthma attack
X101z	Allergic asthma NEC
X1020	Hay fever with asthma
X1021	Allergic non-atopic asthma
X1022	Intrinsic asthma with asthma attack
X1024	Aspirin-sensitive asthma with nasal polyps
X102D	Status asthmaticus
XE0YQ	Allergic atopic asthma
XE0YR	Extrinsic asthma without status asthmaticus
XE0YS	Extrinsic asthma with status asthmaticus
XE0YT	Non-allergic asthma
XE0YU	Intrinsic asthma with status asthmaticus
XE0YV	Status asthmaticus NOS
XE0YW	Asthma attack
XE0YX	Asthma NOS
XE0ZP	Extrinsic asthma - atopy (& pollen)
XE0ZR	Asthma: [intrinsic] or [late onset]
XE0ZT	Asthma: [NOS] or [attack]
XM0s2	Asthma attack NOS
Xa0lZ	Asthmatic bronchitis

Xa9zf	Acute asthma
XaLPE	Nocturnal asthma
Xaa7B	Chronic asthma with fixed airflow obstruction
Xac33	Asthma-chronic obstructive pulmonary disease overlap syndrome
Xafdj	Acute severe exacerbation of asthma
Xafdy	Moderate acute exacerbation of asthma
Xafdz	Life threatening acute exacerbation of asthma

8.5 SABA Read Codes

read_code	MX_PRODUCT_NAME
c12w.	SALBUTAMOL inh 100micrograms/inhalation
c131.	ASMAVEN inh 100micrograms
c133.	SALBULIN inh
c134.	VENTOLIN inh 100micrograms/inhalation
c136.	VENTOLIN rcap 200micrograms
c137.	VENTOLIN rcap 400micrograms
c13C.	SALBUTAMOL disc 200micrograms
c13D.	SALBUTAMOL disc 400micrograms
c13E.	VENTODISKS disc 400micrograms/blister
c13F.	VENTODISKS disc 200micrograms/blister
c13G.	VENTODISKS disc 400micrograms/blister
c13H.	SALAMOL inh 100micrograms/actuation
c13I.	AIROMIR cfc free inh 100micrograms/inhalation
c13J.	VENTOLIN inh 100micrograms/inhalation
c13K.	SALAMOL EASI-BREATHE breath act inh 100micrograms/actuation
c13L.	VENTOLIN ACCUHALER 200micrograms/actuation
c13M.	VENTOLIN ACCUHALER 200micrograms/actuation
c13N.	SALBUTAMOL vortex inh 100micrograms/inhalation
c13P.	SALBUTAMOL spacehaler 100micrograms/inhalation
c13Q.	SALBUTAMOL CYCLOCAPS inh caps 200micrograms [APS]
c13R.	SALBUTAMOL breath act pwdr inh 200micrograms/actuation
c13S.	SALBUTAMOL breath act pwdr inh 95micrograms
c13T.	VENTOLIN inh 100micrograms/inhalation
c13U.	SALBUTAMOL breath act inh 100micrograms/actuation
c13V.	SALBUTAMOL inh 100micrograms/inhalation
c13Y.	SALAMOL inh 100micrograms/actuation
c13c.	AEROLIN AUTOHALER breath act inh 100micrograms/actuation
c13d.	VENTODISKS disc 200micrograms/blister
c13e.	VENTODISKS disc 400micrograms/blister
c13f.	VENTODISKS disc 200micrograms/blister
c13g.	VENTODISKS disc 400micrograms/blister

c13h.	SALBUVENT inh 100micrograms/actuation
c13l.	AEROLIN AUTOHALER breath act inh 100micrograms/actuation
c13n.	AEROLIN AUTOHALER breath act inh 100micrograms/actuation
c13p.	MAXIVENT inh 100micrograms/inhalation
c13q.	SALBUTAMOL inh caps 200micrograms
c13r.	SALBUTAMOL inh caps 400micrograms
c13v.	SALBUTAMOL inh 100micrograms/inhalation
c13x.	SALBUTAMOL inh caps 200micrograms
c13y.	SALBUTAMOL inh caps 400micrograms
c144.	BRICANYL inh
c145.	BRICANYL refill canister
c146.	BRICANYL spacer inh
c14f.	BRICANYL TURBOHALER 500micrograms
c14g.	BRICANYL TURBOHALER 500micrograms
c14j.	BRICANYL TURBOHALER 500micrograms
c14t.	TERBUTALINE inh 250micrograms/actuation
c14u.	TERBUTALINE inh 250micrograms/actuation
c14v.	TERBUTALINE inh 250micrograms/actuation
c151.	BEROTEC inh 200micrograms/actuation
c153.	BEROTEC inh 100micrograms/actuation
c154.	FENOTEROL inh 100micrograms/actuation
c15y.	FENOTEROL inh 200micrograms/actuation
c173.	BRONCHODIL inh 500micrograms/dose
c17y.	REPROTEROL inh 500micrograms/dose
c181.	PULMADIL inh
c182.	PULMADIL inh
c183.	PULMADIL AUTO inh
c18z.	RIMITEROL inh
c1E1.	SALAMOL EASI-BREATHE breath act inh 100micrograms/actuation
c1E2.	PULVINAL SALBUTAMOL breath act pwdr inh 200micrograms/actuation
c1E3.	VENTODISKS disc 200micrograms/blister
c1E4.	VENTODISKS disc 400micrograms/blister
c1E5.	VENTODISKS disc 200micrograms/blister
c1E6.	VENTODISKS disc 400micrograms/blister
c1E7.	EASYHALER SALBUTAMOL breath act pwdr inh 100micrograms/actuation
c1E8.	EASYHALER SALBUTAMOL breath act pwdr inh 200micrograms/actuation
c1E9.	SALBULIN inh
c1EA.	SALBUTAMOL breath act pwdr inh 100micrograms/actuation
c1EC.	SALBUTAMOL disc 400micrograms
c51A.	DUOVENT inh 40micrograms + 100micrograms/actuation
c51B.	FENOTEROL + IPRATROPIUM BROMIDE breath act inh 100micrograms + 40micrograms/actuation

c51C.	IPRATROPIUM BROMIDE + SALBUTAMOL inh 20mcg + 100mcg
c51D.	COMBIVENT inh 20mcg + 100mcg
c51i.	DUOVENT inh 40micrograms + 100micrograms/actuation
c51x.	DUOVENT AUTOHALER breath act inh
c621.	VENTIDE inh
c622.	VENTOLIN rcap 200micrograms
c623.	VENTIDE paed rcap
c722.	AEROCROM inh
c72y.	SODIUM CROMOGLICATE + SALBUTAMOL inh & spacer
c72z.	SODIUM CROMOGLICATE + SALBUTAMOL inh
i966.	VENTOLIN inh 100micrograms/inhalation
x00Af	SALBUTAMOL inh 100micrograms/inhalation
x02Xr	COMBIVENT inh 20mcg + 100mcg
x02qI	SALAMOL inh 100micrograms/actuation
x02uD	VENTOLIN ACCUHALER 200micrograms/actuation

8.6 SAMA Read codes

read_code	MX_PRODUCT_NAME
c311.	ATROVENT inh 20micrograms/actuation
c312.	ATROVENT UDVs neb soln 500micrograms/2ml
c313.	ATROVENT FORTE inh 40micrograms/actuation
c314.	ATROVENT UDVs neb soln 0.25mg/ml
c315.	ATROVENT AUTOHALER breath act inh 20micrograms/actuation
c316.	STERI-NEB IPRATROPIUM unit dose neb soln 250micrograms/ml
c317.	STERI-NEB IPRATROPIUM unit dose neb soln 250micrograms/ml
c318.	ATROVENT AEROCAPS 40mcg
c319.	ATROVENT AEROHALER 40mcg
c31A.	IPRATROPIUM BROMIDE inh caps 40mcg
c31B.	IPRATROPIUM BROMIDE caps + inh 40mcg
c31C.	RESPONTIN NEBULES 250micrograms/ml
c31D.	RESPONTIN NEBULES 250micrograms/ml
c31F.	TROPIOVENT STERIPOULE unit dose neb soln 250micrograms/ml
c31G.	ATROVENT cfc free inh 20micrograms/actuation
c31t.	IPRATROPIUM BROMIDE cfc free inh 20micrograms/actuation
c31u.	IPRATROPIUM BROMIDE inh 20micrograms/dose
c31v.	IPRATROPIUM BROMIDE unit dose neb soln 250micrograms/ml
c31w.	IPRATROPIUM BROMIDE unit dose neb soln 250micrograms/ml
c31x.	IPRATROPIUM BROMIDE inh 20micrograms/dose
c31y.	STERI-NEB IPRATROPIUM unit dose neb soln 250micrograms/ml
c31z.	IPRATROPIUM BROMIDE inh 40micrograms/metered inhalation
c51A.	DUOVENT inh 40micrograms + 100micrograms/actuation

c51B.	FENOTEROL + IPRATROPIUM BROMIDE breath act inh 100micrograms + 40micrograms/actuation
c51C.	IPRATROPIUM BROMIDE + SALBUTAMOL inh 20mcg + 100mcg
c51D.	COMBIVENT inh 20mcg + 100mcg
c51E.	COMBIVENT UDVs neb soln 2.5ml
c51F.	IPRATROPIUM BROMIDE + SALBUTAMOL unit dose neb soln 500micrograms + 2.5mg/2.5ml
c51H.	SALBUTAMOL + IPRATROPIUM BROMIDE unit dose neb soln 2.5mg + 500micrograms/2.5ml
c51i.	DUOVENT inh 40micrograms + 100micrograms/actuation
c51v.	DUOVENT UDVs neb soln
c51w.	IPRATROPIUM BROMIDE + SALBUTAMOL unit dose neb soln 500micrograms + 2.5mg/2.5ml
c51x.	DUOVENT AUTOHALER breath act inh
c531.	IPRAMOL STERI-NEB unit dose neb soln 500micrograms + 2.5mg/2.5ml
x02Uk	ATROVENT AEROCAPS 40mcg
x02Xr	COMBIVENT inh 20mcg + 100mcg

8.7 ICS Read Codes

read_code	MX_PRODUCT_NAME
c611.	BECLOFORTE inh 250micrograms/actuation
c612.	BECOTIDE 50 inh 50micrograms/actuation
c613.	BECOTIDE rcap 100micrograms
c614.	BECOTIDE rcap 200micrograms
c617.	BECOTIDE 100 inh 100micrograms/actuation
c619.	BECODISKS disc 100micrograms
c61A.	BECODISKS disc 200micrograms
c61B.	BECOTIDE rcap 400micrograms
c61C.	BECODISKS disc 100micrograms
c61D.	BECODISKS disc 200micrograms
c61E.	BECLOMETASONE breath act inh 250micrograms/actuation
c61F.	BECLOMETASONE breath act inh 100micrograms/actuation
c61G.	FILAIR inh 50micrograms/actuation
c61H.	FILAIR inh 100micrograms/actuation
c61J.	FILAIR FORTE inh 250micrograms/actuation
c61K.	BECLAZONE inh 50micrograms/actuation
c61L.	BECLAZONE inh 100micrograms/actuation
c61M.	BECLAZONE inh 250micrograms/actuation
c61N.	BECLOFORTE disks (refill pack) 400micrograms/actuation
c61O.	BECLOMETASONE breath act inh 100micrograms/actuation
c61P.	BECLOMETASONE disc 100micrograms

c61Q.	BECLOFORTE INTEGRA inh/compt spacer 250micrograms/actuation
c61R.	BECLOFORTE INTEGRA inh/compt spacer 250micrograms/actuation
c61S.	BECLOMETASONE inh/compt spacer 250micrograms/actuation
c61T.	BECLOMETHASONE breath act inh 250micrograms/actuation [APS]
c61V.	BECLOMETASONE vortex inh 50micrograms/actuation
c61W.	BECLOMETASONE inh caps 100micrograms
c61X.	BECLOMETASONE inh 100micrograms/actuation
c61Y.	BDP spacehaler 100micrograms/actuation
c61Z.	BECLOMETASONE vortex inh 250micrograms/actuation
c61a.	BECODISKS disc 200micrograms
c61b.	BECOTIDE rcap 400micrograms
c61c.	BECODISKS disc 100micrograms
c61d.	BECODISKS disc 200micrograms
c61e.	BECODISKS disc 400micrograms
c61f.	BECODISKS disc 400micrograms
c61g.	FILAIR inh 50micrograms/actuation
c61h.	FILAIR inh 100micrograms/actuation
c61i.	BECOTIDE 200 inh 200micrograms/actuation
c61j.	AEROBEC AUTOHALER 50micrograms/actuation
c61k.	AEROBEC forte AUTOHALER 250micrograms/actuation
c61l.	AEROBEC AUTOHALER 100micrograms/actuation
c61m.	BECLOFORTE DISKHALER 400micrograms/actuation
c61n.	BECLOFORTE disks (refill pack) 400micrograms/actuation
c61p.	BECLOMETASONE disc 100micrograms
c61q.	BECLOMETASONE disc 200micrograms
c61r.	BECLOMETASONE inh 100micrograms/actuation
c61s.	BECLOMETASONE disc 200micrograms
c61t.	BECLOMETASONE inh 250micrograms/actuation
c61u.	BECLOMETASONE inh 200micrograms/actuation
c61v.	BECOTIDE 50 inh 50micrograms/actuation
c61w.	BECLOMETASONE inh caps 100micrograms
c61x.	BECLOMETASONE inh caps 200micrograms
c61z.	BECOTIDE 100 inh 100micrograms/actuation
c621.	VENTIDE inh
c641.	PULMICORT inh 200micrograms
c643.	PULMICORT refill canister 200micrograms
c644.	PULMICORT LS inh 50micrograms
c645.	PULMICORT LS refill canister 50micrograms
c647.	PULMICORT inh 200micrograms
c648.	PULMICORT TURBOHALER breath act pwdr inh 200micrograms/actuation
c649.	PULMICORT TURBOHALER breath act pwdr inh 400micrograms/actuation
c64A.	BUDESONIDE inh 200micrograms/actuation

c64B. BUDESONIDE inh 50micrograms/actuation
c64C. PULMICORT inh 200micrograms
c64D. PULMICORT LS inh 50micrograms
c64E. PULMICORT inh 200micrograms
c64F. BUDESONIDE dry pdr inh cart ref 200micrograms
c64G. NOVOLIZER BUDESONIDE inh pdr (refill) 200micrograms
c64H. EASYHALER BUDESONIDE breath act pwdr inh 100micrograms/actuation
c64I. EASYHALER BUDESONIDE breath act pwdr inh 200micrograms/actuation
c64J. EASYHALER BUDESONIDE breath act pwdr inh 400micrograms/actuation
c64K. BUDESONIDE inh 100micrograms/actuation
c64L. BUDESONIDE inh 100micrograms/actuation
c64M. PULMICORT inh 200micrograms
c64N. BUDESONIDE inh 200micrograms/actuation
c64c. PULMICORT TURBOHALER breath act pwdr inh 100micrograms/actuation
c64d. BUDESONIDE breath act pwdr inh 100micrograms/actuation
c64e. PULMICORT inh 200micrograms
c64g. BUDESONIDE breath act pwdr inh 200micrograms/actuation
c64h. BUDESONIDE breath act pwdr inh 400micrograms/actuation
c64m. BUDESONIDE inh caps 200micrograms
c64n. BUDESONIDE inh caps 400micrograms
c64o. BUDESONIDE inh 200micrograms/actuation
c64p. NOVOLIZER BUDESONIDE inh pdr + device 200micrograms
c64u. BUDESONIDE dry pdr inh cart+dev 200micrograms
c64v. BUDESONIDE inh 200micrograms/actuation
c64x. BUDESONIDE inh 200micrograms/actuation
c64y. BUDESONIDE inh 50micrograms/actuation
c64z. BUDESONIDE inh 200micrograms/actuation
c651. FLIXOTIDE disc 50micrograms
c652. FLIXOTIDE disc 100micrograms
c653. FLIXOTIDE disc 250micrograms
c654. FLUTICASONE disc 500micrograms
c655. FLUTICASONE disc 100micrograms
c656. FLUTICASONE disc 250micrograms
c657. FLIXOTIDE disc 50micrograms
c658. FLIXOTIDE disc 100micrograms
c65A. FLUTICASONE disc 50micrograms
c65B. FLIXOTIDE disc 100micrograms
c65C. FLIXOTIDE disc 250micrograms
c65D. FLIXOTIDE inh 25micrograms/actuation
c65E. FLIXOTIDE inh 50micrograms/actuation
c65F. FLIXOTIDE inh 125micrograms/actuation
c65G. FLUTICASONE inh 25micrograms/actuation

c65H. FLUTICASONE inh 50micrograms/actuation
c65I. FLUTICASONE inh 50micrograms/actuation
c65J. FLUTICASONE inh 250micrograms/actuation
c65K. FLIXOTIDE inh 250micrograms/actuation
c65L. FLIXOTIDE disc 500micrograms
c65M. FLIXOTIDE disc 500micrograms
c65N. FLUTICASONE disc 500micrograms
c65O. FLUTICASONE disc 500micrograms
c65P. FLUTICASONE breath act pwdr inh 50micrograms/inhalation
c65Q. FLUTICASONE breath act pwdr inh 100micrograms/inhalation
c65R. FLIXOTIDE ACCUHALER 250micrograms/inhalation
c65S. FLUTICASONE breath act pwdr inh 500micrograms/inhalation
c65T. FLIXOTIDE ACCUHALER 50micrograms/inhalation
c65U. FLIXOTIDE ACCUHALER 100micrograms/inhalation
c65V. FLIXOTIDE ACCUHALER 250micrograms/inhalation
c65W. FLIXOTIDE ACCUHALER 500micrograms/inhalation
c65b. FLUTICASONE cfc free inh 125micrograms/actuation
c65c. FLUTICASONE cfc free inh 250micrograms/actuation
c65d. FLIXOTIDE EVOHALER 125micrograms/actuation
c65e. FLIXOTIDE EVOHALER 250micrograms/actuation
c65f. FLUTICASONE cfc free inh 50micrograms/actuation
c65g. FLUTICASONE inh 25micrograms/actuation
c661. ASMABEC spacehaler 250micrograms/actuation
c662. BECOTIDE EASI-BREATHE breath act inh 50micrograms/actuation
c663. BECOTIDE EASI-BREATHE breath act inh 100micrograms/actuation
c664. BECLOFORTE EASI-BREATHE breath act inh 250micrograms/actuation
c665. QVAR cfc free inh 50micrograms/actuation
c666. QVAR cfc free inh 100micrograms/actuation
c667. QVAR AUTOHALER cfc/free b/act inh 50micrograms/actuation
c668. QVAR AUTOHALER cfc/free b/act inh 100micrograms/actuation
c669. BECLAZONE inh 200micrograms/actuation
c66A. BECLOMETASONE breath act inh 50micrograms/actuation
c66B. BECLOMETASONE breath act pwdr inh 100micrograms/actuation
c66C. BECLOMETASONE breath act inh 250micrograms/actuation
c66D. ASMABEC CLICKHALER dry pdr inh 50micrograms
c66E. ASMABEC CLICKHALER dry pdr inh 100micrograms
c66F. BECLOMETASONE breath act pwdr inh 250micrograms/actuation
c66G. BECLOMETASONE breath act pwdr inh 400micrograms/actuation
c66H. BECLOMETASONE breath act pwdr inh 200micrograms/actuation
c66I. PULVINAL BECLOMETASONE DIPROPIONATE breath act pwdr inh 100micrograms/actuation

c66J.	PULVINAL BECLOMETASONE DIPROPIONATE breath act pwdr inh 200micrograms/actuation
c66K.	PULVINAL BECLOMETASONE DIPROPIONATE breath act pwdr inh 400micrograms/actuation
c66L.	BECLOMETASONE CYCLOCAPS inh caps 100micrograms [APS]
c66M.	BECLOMETASONE CYCLOCAPS inh caps 200micrograms [APS]
c66N.	BECLOMETASONE CYCLOCAPS inh caps 400micrograms [APS]
c66P.	BECODISKS disc 100micrograms
c66Q.	BECODISKS disc 200micrograms
c66R.	BECODISKS disc 400micrograms
c66S.	BECODISKS disc 100micrograms
c66T.	BECOTIDE 200 inh 200micrograms/actuation
c66U.	BECODISKS disc 400micrograms
c66V.	BECLOMETASONE EXTRAFINE PARTICLE cfc free inh 50micrograms/actuation
c66W.	BECLOMETASONE EXTRAFINE PARTICLE cfc free inh 100micrograms/actuation
c66X.	BECLOMETASONE breath act inh 50micrograms/actuation
c66Y.	BECLOMETASONE breath act inh 100micrograms/actuation
c66Z.	QVAR EASI-BREATHE cfc/free b/act inh 50micrograms/actuation
c66a.	QVAR EASI-BREATHE cfc/free b/act inh 100micrograms/actuation
c66b.	EASYHALER BECLOMETASONE breath act pwdr inh 200micrograms/actuation
c66c.	CLENIL MODULITE cfc free inh 50micrograms/actuation
c66d.	CLENIL MODULITE cfc free inh 100micrograms/actuation
c66e.	CLENIL MODULITE cfc free inh 200micrograms/actuation
c66f.	CLENIL MODULITE cfc free inh 250micrograms/actuation
c66g.	BECLOMETASONE cfc free inh 200micrograms/actuation
c66h.	BECLOMETASONE cfc free inh 250micrograms/actuation
c681.	MOMETASONE FUROATE dry pdr inh 200micrograms/actuation
c682.	MOMETASONE FUROATE dry pdr inh 400micrograms/actuation
c683.	ASMANEX TWISTHALER dry pdr inh 200micrograms/actuation
c684.	ASMANEX TWISTHALER dry pdr inh 400micrograms/actuation
c691.	ALVESCO cfc free inh 160micrograms/actuation
c692.	ALVESCO cfc free inh 80micrograms/actuation
c69y.	CICLESONIDE cfc free inh 80micrograms/actuation
c69z.	CICLESONIDE cfc free inh 160micrograms/actuation
p436.	BECLOFORTE VM pack 250micrograms/actuation
x00Hz	BECODISKS disc 200micrograms
x00I0	BECODISKS disc 400micrograms
x00QU	PULMICORT inh 200micrograms
x00gE	PULMICORT TURBOHALER breath act pwdr inh 100micrograms/actuation
x00gF	PULMICORT TURBOHALER breath act pwdr inh 200micrograms/actuation
x00gG	PULMICORT TURBOHALER breath act pwdr inh 400micrograms/actuation
x01MQ	BECLOMETASONE inh 100micrograms/actuation

x02Mk	BUDESONIDE inh 200micrograms/actuation
x02ct	FLIXOTIDE ACCUHALER 100micrograms/inhalation
x03d9	PULMICORT inh 200micrograms

8.8 LABA & ICS/LABA Read codes

read_code	MX_PRODUCT_NAME
c19..	SALMETEROL inh 25micrograms/actuation
c191.	SALMETEROL inh 25micrograms/actuation
c192.	SEREVENT inh 25micrograms/actuation
c193.	SEREVENT DISKHALER 50micrograms
c194.	SEREVENT DISKHALER 50micrograms
c195.	SALMETEROL disc 50micrograms
c196.	SALMETEROL disc 50micrograms
c197.	SALMETEROL disc 50micrograms
c198.	SEREVENT ACCUHALER 50micrograms/actuation
c199.	SEREVENT inh 25micrograms/actuation
c19A.	SALMETEROL inh 25micrograms/actuation
c19B.	SALMETEROL inh 25micrograms/actuation
c19z.	SALMETEROL disc 50micrograms
c1C1.	FORMOTEROL FUMARATE inh caps 12mcg
c1C2.	FORADIL inh caps 12mcg
c1C3.	FORMOTEROL FUMARATE breath act inh 6 micrograms/actuation
c1C4.	FORMOTEROL FUMARATE breath act inh 12micrograms/actuation
c1C5.	OXIS 6 TURBOHALER 6 micrograms/actuation
c1C6.	OXIS 12 TURBOHALER 12micrograms/actuation
c1C7.	ATIMOS MODULITE cfc free inh 12micrograms/actuation
c1C8.	FORMOTEROL FUMARATE breath act inh 12micrograms/actuation
c1Cz.	FORMOTEROL FUMARATE breath act inh 12micrograms/actuation
c1D1.	SERETIDE 100 ACCUHALER
c1D2.	SERETIDE 250 ACCUHALER
c1D3.	SERETIDE 500 ACCUHALER
c1D4.	SERETIDE 50 EVOHALER 25micrograms + 50micrograms/actuation
c1D5.	SERETIDE 125 EVOHALER 25micrograms + 125micrograms/actuation
c1D6.	SERETIDE 250 EVOHALER 25micrograms + 250micrograms/actuation
c1D7.	SIRDUPLA 25micrograms/125micrograms inhaler
c1D8.	SIRDUPLA 25micrograms/250micrograms inhaler
c1D9.	AIRFLUSAL FORSPIRO 50micrograms/500micrograms pdr inhaler
c1Du.	FLUTICASONE + SALMETEROL cfc free inh 50micrograms + 25micrograms/actuation
c1Dv.	FLUTICASONE + SALMETEROL cfc free inh 125micrograms + 25micrograms/actuation
c1Dw.	FLUTICASONE + SALMETEROL cfc free inh 250micrograms + 25micrograms/actuation
c1Dx.	FLUTICASONE + SALMETEROL dry pdr inh 100micrograms + 50micrograms/inhalation

c1Dy.	FLUTICASONE + SALMETEROL dry pdr inh 250micrograms + 50micrograms/inhalation
c1Dz.	FLUTICASONE + SALMETEROL dry pdr inh 500micrograms + 50micrograms/inhalation
c1b1.	ONBREZ BREEZHALER capsules for inhalation + inhaler 150micrograms [NOVARTIS]
c1b2.	ONBREZ BREEZHALER capsules for inhalation + inhaler 150micrograms [NOVARTIS]
c1b3.	ONBREZ BREEZHALER capsules for inhalation + inhaler 300micrograms [NOVARTIS]
c1b4.	ONBREZ BREEZHALER capsules for inhalation + inhaler 300micrograms [NOVARTIS]
c1c1.	Flutiform Cfc-free inhaler 50 micrograms + 5 micrograms/dose 120 doses
c1c2.	Flutiform Cfc-free inhaler 125 micrograms + 5 micrograms/dose 120 doses
c1c3.	Flutiform Cfc-free inhaler 250 micrograms + 10 micrograms/dose 120 doses
c1cx.	Flutiform Cfc-free inhaler 250 micrograms + 10 micrograms/dose 120 doses
c1cy.	Flutiform Cfc-free inhaler 125 micrograms + 5 micrograms/dose 120 doses
c1cz.	Flutiform Cfc-free inhaler 50 micrograms + 5 micrograms/dose 120 doses
c1d1.	STRIVERDI RESPIMAT 2.5micrograms inhaler
c1d2.	OLODATEROL 2.5micrograms inhaler
c671.	SYMBICORT TURBOHALER 100micrograms + 6micrograms/actuation
c672.	SYMBICORT TURBOHALER 200micrograms + 6micrograms/actuation
c673.	SYMBICORT TURBOHALER 400micrograms + 12micrograms/actuation
c674.	DUORESP SPIROMAX 160mcg/4.5mcg breath-act dry powder inhaler
c675.	DUORESP SPIROMAX 320mcg/9mcg breath-act dry powder inhaler
c67x.	BUDESONIDE + FORMOTEROL breath act pwdr inh 400micrograms + 12micrograms/actuation
c67y.	BUDESONIDE + FORMOTEROL breath act pwdr inh 200micrograms + 6micrograms/actuation
c67z.	SYMBICORT TURBOHALER 100micrograms + 6micrograms/actuation
c6A1.	FOSTAIR cfc free inh 100micrograms + 6micrograms/actuation
c6A2.	FOSTAIR NEXTHALER 100micrograms + 6micrograms powder inhaler
c6A3.	FOSTAIR 200micrograms/6micrograms inhaler
c6A4.	FOSTAIR NEXTHALER 200micrograms/6micrograms powder inhaler
c6Aw.	BECLOMET DIPROP+FORMOTERL FUMARATE DIHYD 200mcg/6mcg pdr inh
c6Ax.	BECLOMET DIPROP+FORMOTERL FUMARATE DIHYD 200mcg/6mcg inhaler
c6Ay.	BECLOMET DIPROP+FORMOTERL FUMARATE DIHYD 100mcg/6mcg pdr inh
c6Az.	BECLOMETASONE + FORMOTEROL 100 micrograms + 6 micrograms/dose
c6B1.	RELVAR ELLIPTA 184micrograms/22micrograms inhaler
c6B2.	FLUTICASONE FUROATE+VILANTEROL 184mcg/22mcg dry pdr inhaler
c6B3.	RELVAR ELLIPTA 92micrograms/22micrograms inhaler
c6B4.	FLUTICASONE FUROATE+VILANTEROL 92mcg/22mcg dry pdr inhaler
x02qr	SEREVENT ACCUHALER 50micrograms/actuation
x04xm	SERETIDE 100 ACCUHALER
x0594	SERETIDE 125 EVOHALER 25micrograms + 125micrograms/actuation
x05J2	SYMBICORT TURBOHALER 100micrograms + 6micrograms/actuation

8.9 LAMA Read codes

read_code	MX_PRODUCT_NAME
c33..	TIOTROPIUM inh caps 18 micrograms
c331.	TIOTROPIUM inh pdr cap (refill) 18 micrograms
c332.	TIOTROPIUM inh caps 18 micrograms
c333.	Spiriva Respimat Solution For Inhalation 2.5 micrograms/puff 60 puffs
c33x.	Spiriva Respimat Solution For Inhalation 2.5 micrograms/puff 60 puffs
c33y.	SPIRIVA inh pdr caps+dev 18 micrograms
c33z.	SPIRIVA inh caps 18 micrograms
c341.	EKLIRA GENUAIR inhalation powder 322micrograms
c342.	Aclidinium Bromide Dry Powder Inhaler 375 micrograms/dose
c351.	Incruse Ellipta 55micrograms/dose dry powder inhaler
c352.	UMECLIDINIUM 55micrograms/dose dry powder inhaler
o323.	SEEBRI BREEZHALER 44micrograms inhalation capsules
o324.	GLYCOPYRRONIUM 44micrograms inhalation capsules
x05gG	SPIRIVA inh pdr cap (refill) 18 micrograms

8.10 LABA/LAMA Read codes

read_code	read_term
c1e..	INDACATEROL+GLYCOPYRRONIUM
c1e1.	ULTIBRO BREEZHALER 85mcg/43mcg inh powder capsules+inhaler
c1e2.	INDACATEROL+GLYCOPYRRONIUM 85mcg/43mcg inh powder caps+inh
c51I.	ANORO ELLIPTA 55micrograms/22micrograms dry powder inhaler
c51J.	UMECLIDINIUM+VILANTEROL 55mcg/22mcg dry powder inhaler
c51K.	DUAKLIR GENUAIR 340micrograms/12micrograms powder inhaler
c51L.	ACLIDINIUM+FORMOTEROL FUMARATE DIHYD 340mcg/12mcg pdr inh
c51M.	SPIOLTO RESPIMAT 2.5micrograms/2.5micrograms inhaler
c51N.	TIOTROPIUM+OLODATEROL 2.5micrograms/2.5micrograms inhaler

8.11 LTRA Read codes

read_code	MX_PRODUCT_NAME
cA11.	MONTELUKAST (AS SODIUM SALT) tabs 10mg
cA12.	SINGULAIR paed chewable tab 5mg
cA13.	SINGULAIR tabs 10mg
cA14.	SINGULAIR paed chewable tab 5mg

cA15.	SINGULAIR paed chewable tab 4mg
cA16.	SINGULAIR paed grans 4mg/sachet
cA1y.	MONTELUKAST (AS SODIUM SALT) grans 4mg/sachet
cA1z.	MONTELUKAST (AS SODIUM SALT) chewable tab 4mg
cA21.	ZAFIRLUKAST tabs 20mg
cA22.	ACCOLATE tabs 20mg
x04cV	SINGULAIR paed chewable tab 4mg

8.12 Theophylline Read codes

read_code	MX_PRODUCT_NAME
c411.	AMINOPHYLLINE tabs 100mg
c412.	AMINOPHYLLINE inj 250mg/10ml
c413.	AMINOPHYLLINE inj 250mg/ml
c419.	THEODROX tabs
c41B.	NORPHYLLIN SR tablets 225mg
c41a.	PHYLLOCONTIN CONTINUS tabs 225mg
c41b.	PHYLLOCONTIN CONTINUS forte tabs 350mg
c41c.	PHYLLOCONTIN CONTINUS paed tab 100mg
c41d.	AMINOPHYLLINE SR tablets 225mg [IVAX]
c41f.	AMINOPHYLLINE HYDRATE mr tab 350mg
c41g.	AMINOPHYLLINE mr tab 100mg
c41h.	AMNIVENT sr tab 225mg
c41k.	AMINOPHYLLINE inj 25mg/ml [CELLTECH]
c41m.	AMINOPHYLLINE HYDRATE mr tab 225mg
c421.	CHOLEDYL tabs 100mg
c422.	CHOLEDYL tabs 200mg
c423.	CHOLEDYL syrp 62.5mg/5ml
c42w.	CHOLINE THEOPHYLLINATE tabs 100mg
c42x.	CHOLINE THEOPHYLLINATE tabs 200mg
c431.	BIOPHYLLINE syrp 125mg/5ml
c432.	NUELIN tabs 125mg
c433.	NUELIN liq 60mg/5ml
c434.	LASMA tabs 300mg
c435.	NUELIN SA tabs 175mg

c436.	NUELIN SA-250 tabs
c437.	PRO-VENT caps 300mg
c438.	SLO-PHYLLIN caps 60mg
c439.	SLO-PHYLLIN caps 125mg
c43a.	SLO-PHYLLIN caps 250mg
c43b.	THEO-DUR tabs 200mg
c43c.	THEO-DUR tabs 300mg
c43e.	UNIPHYLLIN CONTINUS tabs 400mg
c43f.	UNIPHYLLIN CONTINUS tabs 200mg
c43h.	UNIPHYLLIN CONTINUS tabs 300mg
c43m.	THEOPHYLLINE syrp 125mg/5ml
c43n.	THEOPHYLLINE tabs 125mg
c43o.	THEOPHYLLINE liq 60mg/5ml
c43p.	THEOPHYLLINE mr tab 175mg
c43q.	THEOPHYLLINE mr tab 250mg
c43r.	THEOPHYLLINE mr tab 300mg
c43s.	THEOPHYLLINE mr cap 60mg
c43t.	THEOPHYLLINE mr cap 125mg
c43u.	THEOPHYLLINE mr cap 250mg
c43v.	THEOPHYLLINE mr tab 200mg
c43w.	THEOPHYLLINE mr tab 300mg
c43x.	THEOPHYLLINE mr tab 350mg
c43y.	THEOPHYLLINE mr tab 400mg
c43z.	THEOPHYLLINE mr tab 200mg
c51t.	FRANOL tabs
c51u.	FRANOL PLUS tabs
x02lT	NUELIN tabs 125mg
x02tm	UNIPHYLLIN CONTINUS tabs 200mg

8.13 ICS/LABA/LAMA Snowmed codes

snomed	nm
34681611000001100	Trimbow 87micrograms/dose / 5micrograms/dose / 9micrograms/dose inhaler
34683311000001106	Generic Trimbow 87micrograms/dose / 5micrograms/dose / 9micrograms/dose inhaler
34952211000001104	Trelegy Ellipta 92micrograms/dose / 55micrograms/dose / 22micrograms/dose dry powder inhaler
34955111000001103	Generic Trelegy Ellipta 92micrograms/dose / 55micrograms/dose / 22micrograms/dose dry powder inhaler

8.14 Oral Steroids Read codes

read_code	read_term
fe3..	DEXAMETHASONE [ENDOCRINE]
fe31.	DEXAMETHASONE 500micrograms tablets
fe32.	DEXAMETHASONE 2mg tablets
fe33.	DECADRON 500micrograms tablets
fe36.	*ORADEXON 500microgram tablets
fe37.	*ORADEXON 2mg tablets
fe3A.	DEXSOL 2mg/5mL oral solution
fe3B.	DEXAMETHASONE 10mg/5mL oral solution
fe3C.	MARTAPAN 2mg/5mL oral solution
fe3r.	DEXAMETHASONE 500micrograms/5mL solution
fe3s.	DEXAMETHASONE 2mg/5mL sugar free solution
fe3u.	DEXAMETHASONE 2mg/5mL liquid
fe4..	HYDROCORTISONE
fe41.	HYDROCORTISONE 10mg tablets
fe42.	HYDROCORTISONE 20mg tablets
fe43.	*HYDROCORTISTAB 20mg tablets
fe44.	*HYDROCORTONE 10mg tablets
fe45.	*HYDROCORTONE 20mg tablets
fe4e.	PLENADREN 5mg m/r tablets
fe4f.	HYDROCORTISONE 5mg m/r tablets
fe4g.	PLENADREN 20mg m/r tablets
fe4h.	HYDROCORTISONE 20mg m/r tablets
fe5..	METHYLPREDNISOLONE [ENDOCRINE]
fe51.	MEDRONE 2mg tablets
fe52.	MEDRONE 4mg tablets
fe53.	MEDRONE 16mg tablets
fe5f.	MEDRONE 100mg tablets
fe5m.	METHYLPREDNISOLONE 100mg tablets
fe5n.	METHYLPREDNISOLONE 2mg tablets
fe5o.	METHYLPREDNISOLONE 4mg tablets
fe5p.	METHYLPREDNISOLONE 16mg tablets
fe6..	PREDNISOLONE [ENDOCRINE]
fe61.	PREDNISOLONE 1mg tablets
fe62.	PREDNISOLONE 5mg tablets
fe64.	*DELTA-PHORICOL 5mg tablets
fe65.	DELTACORTRIL ENTERIC 2.5mg tablets
fe66.	DELTACORTRIL ENTERIC 5mg tablets
fe67.	*DELTALONE 1mg tablets

fe68.	*DELTALONE 5mg tablets
fe69.	*DELTASTAB 1mg tablets
fe6a.	*DELTASTAB 5mg tablets
fe6c.	*PRECORTISYL 1mg tablets
fe6d.	*PRECORTISYL 5mg tablets
fe6e.	PRECORTISYL FORTE 25mg tablets
fe6f.	*PREDNESOL 5mg tablets
fe6g.	*SINTISONE 5mg tablets
fe6h.	PREDNISOLONE 2.5mg e/c tablets
fe6i.	PREDNISOLONE 5mg e/c tablets
fe6j.	PREDNISOLONE 5mg soluble tablets
fe6k.	PREDNISOLONE 50mg tablets
fe6l.	DILACORT 5mg gastro-resistant tablets
fe6m.	DILACORT 2.5mg gastro-resistant tablets
fe6t.	PREDNISOLONE 10mg tablets
fe6v.	*PREDNISOLONE 2.5mg tablets
fe6w.	*PREDNISOLONE 2.5mg tablets
fe6z.	PREDNISOLONE 25mg tablets
fe7..	PREDNISONE
fe71.	*PREDNISONE 1mg tablets
fe72.	*PREDNISONE 5mg tablets
fe73.	*DECORTISYL 5mg tablets
fe74.	*ECONOSONE 1mg tablets
fe75.	*ECONOSONE 5mg tablets
fe76.	Prednisone 20mg tablet
fe77.	LODOTRA 2mg m/r tablets
fe78.	LODOTRA 5mg m/r tablets
fe79.	LODOTRA 1mg m/r tablets
fe7x.	PREDNISONE 5mg m/r tablets
fe7y.	PREDNISONE 2mg m/r tablets
fe7z.	PREDNISONE 1mg m/r tablets
x00yP	Oral prednisolone
x01Mh	Oral dexamethasone
x01Na	Oral hydrocortisone
x01Nb	Oral methylprednisolone

8.15 Ankylosing spondylitis Read codes

Code	Term
388p.	BASDAI - Bath ankylosing spondylitis disease activity index
F5520	Malleus ankylosis
F5521	Ossicle ankylosis (excluding malleus)

J0460	Stiff temporomandibular joint
J0460	Temporomandibular joint ankylosis
N0450	Juvenile ankylosing spondylitis
N085.	Ankylosis of joint
N0851	Joint ankylosis of the shoulder region
N0853	Joint ankylosis of the forearm
N0854	Joint ankylosis of the hand
N0855	Hip joint ankylosis
N0855	Joint ankylosis of the pelvic region and thigh
N0856	Knee joint ankylosis
N0856	Joint ankylosis of the lower leg
N0857	Joint ankylosis of the ankle and foot
N0857	Ankle joint ankylosis
N0858	Joint ankylosis of other specified site
N0859	Ankylosis of multiple joints
N085C	Ankylosis of the elbow joint
N085F	Ankylosis of the wrist joint
N085G	Ankylosis of the 1st CMC joint
N085K	Ankylosis of PIP joint
N085L	Ankylosis of DIP joint
N085M	Ankylosis of the hip joint
N085P	Ankylosis of the knee joint
N085Q	Ankylosis of the ankle joint
N085R	Ankylosis of the subtalar joint
N085S	Ankylosis of other tarsal joint
N085U	Ankylosis of toe joint
N085z	Ankylosis of joint NOS
N10..	Inflammatory spondylopathies
N100.	Ankylosing spondylitis
N100.	Marie - Strumpell spondylitis
N10y.	Other inflammatory spondylopathies
N10y0	Inflammatory spondylopathies in diseases EC
N10yz	Other inflammatory spondylopathies NOS
N10z.	Spondylitis NOS
N117.	Diffuse idiopathic skeletal hyperostosis
N117.	Forestier's disease
N117.	Ankylosing vertebral hyperostosis
N1460	Lumbosacral ankylosis
N1461	Sacroiliac ankylosis
N1462	Sacral ankylosis NOS
N148.	Ankylosis/instability of cervical,thoracic or lumbar spine
N1480	Atlanto-occipital ankylosis

N1481	Atlanto-axial ankylosis
N1482	Cervical spine ankylosis
N1483	Cervico-thoracic ankylosis
N1484	Thoracic spine ankylosis
N1485	Thoraco-lumbar ankylosis
N1486	Lumbar spine ankylosis
N14z.	Ankylosis of spine NOS
N14z.	Spinal disorder NOS
N14z.	Back disorders NOS

8.16 Sjogren's syndrome Read codes

Code	Term
C37z.	Disorder of metabolism NOS
C37z.	Marinesco-Sjogren syndrome
H57y3	Lung disease with Sjogren's disease
N002.	Sicca (Sjogren's) syndrome
N002.	Keratoconjunctivitis sicca
PH12.	Ichthyosiform erythroderma
PH12.	Sjogren - Larsson syndrome

8.17 Systemic lupus erythematosus Read codes

Code	Term
F3710	Polyneuropathy in disseminated lupus erythematosus
F4D33	Eyelid discoid lupus erythematosus
H57y4	Lung disease with systemic lupus erythematosus
K01x4	Nephrotic syndrome in systemic lupus erythematosus
K01x4	Lupus nephritis
M154.	Lupus erythematosus
M1540	Lupus erythematosus chronicus
M1541	Discoid lupus erythematosus
M1542	Lupus erythematosus migrans
M1543	Lupus erythematosus nodularis
M1544	Lupus erythematosus profundus
M1545	Lupus erythematosus tumidus
M1547	Subacute cutaneous lupus erythematosus
M154z	Lupus erythematosus NOS
Myu78	[X]Other local lupus erythematosus
N000.	Systemic lupus erythematosus
N000z	Systemic lupus erythematosus NOS
Nyu43	[X]Other forms of systemic lupus erythematosus

8.18 Ulcerative colitis Read codes

Code	Term
J401z	Crohn's colitis
J401z	Crohn's disease of the large bowel NOS
J402.	Regional ileocolitis
J41..	Ulcerative colitis and/or proctitis
J41..	Idiopathic proctocolitis
J41..	Mucous colitis and/or proctitis
J410.	Ulcerative proctocolitis
J4100	Ulcerative ileocolitis
J4101	Ulcerative colitis
J4102	Ulcerative rectosigmoiditis
J4103	Ulcerative proctitis
J4104	Exacerbation of ulcerative colitis
J410z	Ulcerative proctocolitis NOS
J411.	Ulcerative (chronic) enterocolitis
J412.	Ulcerative (chronic) ileocolitis
J413.	Ulcerative pancolitis
J41y.	Other idiopathic proctocolitis
J41y0	Pseudopolyposis of colon
J41y0	Inflammatory polyps of colon
J41y1	Toxic megacolon
J41yz	Other idiopathic proctocolitis NOS
J41z.	Idiopathic proctocolitis NOS
J43..	Other non-infective inflammatory gastroenteritis and colitis
J43..	Enterocolitis
J43..	Gastroenteritis
J4303	Radiation colitis
J431.	Toxic gastroenteritis
J4310	Toxic gastritis
J4312	Toxic enterocolitis
J4313	Pseudomembranous colitis
J4313	Toxic colitis
J431z	Toxic gastroenteritis NOS
J4323	Allergic colitis
J4333	Dietetic colitis
J436.	Microscopic colitis
J4360	Collagenous colitis
J4361	Lymphocytic colitis
J437.	Colitis

J438.	Left sided colitis
J4z3.	Non-infective colitis NOS
J4z5.	Exacerbation of non-infective colitis
J4z6.	Indeterminate colitis
J521.	Pseudomembranous colitis
J521.	Spastic colon
J521.	Irritable bowel syndrome
J521.	Irritable colon - Irritable bowel syndrome
J5210	Irritable bowel syndrome with diarrhoea
Jyu41	[X]Other ulcerative colitis
N0310	Arthropathy in ulcerative colitis
N0454	Juvenile arthritis in ulcerative colitis

8.19 Polymyalgia rheumatica

N20..	Polymyalgia
N20..	Polymyalgia rheumatica
N200.	Giant cell arteritis with polymyalgia rheumatica

8.20 Psoriatic arthritis Read codes

Code	Term
38Va.	Psoriatic Arthritis Impact of Disease 9 questionnaire
M160.	Psoriatic arthropathy
M160.	Psoriatic arthropathy
M1600	Psoriasis spondylitica
N0452	Juvenile arthritis in psoriasis
X701u	
X701v	
X701w	
X7026	
X7027	
XaeFq	

8.21 Multiple sclerosis Read codes

Code	Term
666A.	Multiple sclerosis review
F20..	Disseminated sclerosis
F20..	Multiple sclerosis
F200.	Multiple sclerosis of the brain stem
F201.	Multiple sclerosis of the spinal cord

F202.	Generalised multiple sclerosis
F203.	Exacerbation of multiple sclerosis
F204.	Benign multiple sclerosis
F206.	Primary progressive multiple sclerosis
F207.	Relapsing and remitting multiple sclerosis
F208.	Secondary progressive multiple sclerosis
F20z.	Multiple sclerosis NOS

8.22 Crohn's disease Read codes

Code	Term
J08z9	Orofacial Crohn's disease
J40..	Regional enteritis - Crohn's disease
J40..	Granulomatous enteritis
J40..	Crohn's disease
J400.	Regional enteritis of the small bowel
J4000	Regional enteritis of the duodenum
J4001	Regional enteritis of the jejunum
J4002	Crohn's disease of the terminal ileum
J4003	Crohn's disease of the ileum unspecified
J4004	Crohn's disease of the ileum NOS
J4005	Exacerbation of Crohn's disease of small intestine
J400z	Crohn's disease of the small bowel NOS
J401.	Regional enteritis of the large bowel
J4010	Regional enteritis of the colon
J4011	Regional enteritis of the rectum
J4012	Exacerbation of Crohn's disease of large intestine
J401z	Crohn's colitis
J401z	Crohn's disease of the large bowel NOS
J402.	Regional ileocolitis
J40z.	Regional enteritis NOS
J40z.	Crohn's disease NOS
J4z1.	Non-infective jejunitis NOS
J4z2.	Non-infective ileitis NOS
J4z3.	Non-infective colitis NOS
J4z4.	Non-infective sigmoiditis NOS
J4z5.	Exacerbation of non-infective colitis
J4zz.	Non-infective gastroenteritis NOS
J4zz.	Diarrhoea - presumed non-infectious
Jyu40	[X]Other Crohn's disease
N0311	Arthropathy in Crohn's disease
N0453	Juvenile arthritis in Crohn's disease

8.23 Cancer of respiratory system Read codes

Code	Term
B2...	Malignant neoplasm of respiratory tract and intrathoracic organs
B22..	Malignant neoplasm of trachea, bronchus and lung
B220.	Malignant neoplasm of trachea
B2200	Malignant neoplasm of cartilage of trachea
B2201	Malignant neoplasm of mucosa of trachea
B220z	Malignant neoplasm of trachea NOS
B221.	Malignant neoplasm of main bronchus
B2210	Malignant neoplasm of carina of bronchus
B2211	Malignant neoplasm of hilus of lung
B221z	Malignant neoplasm of main bronchus NOS
B222.	Malignant neoplasm of upper lobe, bronchus or lung
B2220	Malignant neoplasm of upper lobe bronchus
B2221	Malignant neoplasm of upper lobe of lung
B222z	Malignant neoplasm of upper lobe, bronchus or lung NOS
B223.	Malignant neoplasm of middle lobe, bronchus or lung
B2230	Malignant neoplasm of middle lobe bronchus
B2231	Malignant neoplasm of middle lobe of lung
B223z	Malignant neoplasm of middle lobe, bronchus or lung NOS
B224.	Malignant neoplasm of lower lobe, bronchus or lung
B2240	Malignant neoplasm of lower lobe bronchus
B2241	Malignant neoplasm of lower lobe of lung
B224z	Malignant neoplasm of lower lobe, bronchus or lung NOS
B225.	Malignant neoplasm of overlapping lesion of bronchus and lung
B226.	Mesothelioma
B22y.	Malignant neoplasm of other sites of bronchus or lung
B22z.	Malignant neoplasm of bronchus or lung NOS
B23..	Malignant neoplasm of pleura
B230.	Malignant neoplasm of parietal pleura
B231.	Malignant neoplasm of visceral pleura
B232.	Mesothelioma of pleura
B23y.	Malignant neoplasm of other specified pleura
B23z.	Malignant neoplasm of pleura NOS
B24..	Malignant neoplasm of thymus, heart and mediastinum
B242.	Malignant neoplasm of anterior mediastinum
B243.	Malignant neoplasm of posterior mediastinum
B24X.	Malignant neoplasm of mediastinum, part unspecified
B24y.	Malignant neoplasm of other site of heart, thymus and mediastinum
B24z.	Malignant neoplasm of heart, thymus and mediastinum NOS

B25..	Malignant neoplasm, overlapping lesion of heart, mediastinum and pleura
B26..	Malignant neoplasm, overlapping lesion of respiratory and intrathoracic organs
B2z..	Malignant neoplasm of other and ill-defined sites within the respiratory and intrathoracic organs
B2z0.	Malignant neoplasm of upper respiratory tract, part unspecified
B2zy.	Malignant neoplasm of other site of respiratory tract
B2zz.	Malignant neoplasm of respiratory tract NOS
B57..	Secondary malignant neoplasm of respiratory and digestive systems
B570.	Secondary malignant neoplasm of lung
B571.	Secondary malignant neoplasm of mediastinum
B572.	Secondary malignant neoplasm of pleura
B573.	Secondary malignant neoplasm of other respiratory organs
B57z.	Secondary malignant neoplasm of respiratory or digestive system NOS
B81..	Carcinoma in situ of respiratory system
B811.	Carcinoma in situ of trachea
B812.	Carcinoma in situ of bronchus and lung
B8120	Carcinoma in situ of carina of bronchus
B8121	Carcinoma in situ of main bronchus
B8122	Carcinoma in situ of upper lobe bronchus and lung
B8123	Carcinoma in situ of middle lobe bronchus and lung
B8124	Carcinoma in situ of lower lobe bronchus and lung
B812z	Carcinoma in situ of bronchus or lung NOS
B81y.	Carcinoma in situ of other specified parts of respiratory system
B81y0	Carcinoma in situ of pleura
Xa0KF	Tumour of lung
Xa0KG	Malignant tumour of lung
XaFr7	Local recurrence of malignant tumour of lung
X78QF	Malignant tumour of lung parenchyma
X78QG	Adenocarcinoma of lung
XaBAp	Bronchioloalveolar adenocarcinoma of lung
X78QI	Carcinoid tumour of lung
X78QJ	Carcinoma of lung parenchyma
X78QK	Large cell carcinoma of lung
X78QL	Clear cell carcinoma of lung
X78QM	Giant cell carcinoma of lung
X78QN	Small cell carcinoma of lung
X78QO	Oat cell carcinoma of lung
X78QP	Squamous cell carcinoma of lung
X78QQ	Epithelioid haemangioendothelioma of lung
X78QR	Lymphomatoid granulomatosis of lung
Xa3A5	Metastasis to lung of unknown primary
X2032	Pulmonary tumour embolism

X78kX	Secondary lymphangitic carcinoma
X78kY	Lymphangitis carcinomatosa
X78QT	Pancoast tumour
XE1yN	Ca middle lobe bronchus/lung
XE1yP	Ca lower lobe bronchus/lung
Byu20	[X]Malignant neoplasm of bronchus or lung, unspecified
XE1vb	Malignant neoplasm of upper lobe, bronchus or lung
XE1yL	Ca upper lobe bronchus/lung
XE1vc	Malignant neoplasm of bronchus or lung NOS
Xa98a	Bronchial adenoma
X78QD	Papilloma of bronchus
X78QW	Histiocytoma of lung
X78QX	Adenoma of lung
X78Q6	Tumour of bronchus
X78Q7	Malignant tumour of bronchus
X78Q8	Squamous cell carcinoma of bronchus
XaEJe	Squamous cell carcinoma of bronchus in left lower lobe
XaEJf	Squamous cell carcinoma of bronchus in left upper lobe
XaEJg	Squamous cell carcinoma of bronchus in right lower lobe
XaEJh	Squamous cell carcinoma of bronchus in right middle lobe
XaEJi	Squamous cell carcinoma of bronchus in right upper lobe
X77nT	Carcinoid bronchial adenoma
X78QS	Non-small cell lung cancer
X78kV	Metastasis to bronchus
Xa3A4	Metastasis to bronchus of unknown primary
XE1yJ	Ca main bronchus
X78QA	Carcinoma in situ of bronchus
X78QE	Tumour of lung parenchyma
X78QU	Carcinoma in situ of lung parenchyma
X78QY	Intrapulmonary teratoma
X78QZ	Hamartoma of lung
X78Py	Tumour of lower respiratory tract

8.24 Rheumatoid arthritis Read Codes

Read Code	Read Term
N040.	Rheumatoid arthritis
X701h	Seropositive rheumatoid arthritis
XaBMO	Seropositive errosive rheumatoid arthritis
Nyu11	[X]Other seropositive rheumatoid arthritis
Nyu1G	[X]Seropositive rheumatoid arthritis, unspecified
X701i	Seronegative rheumatoid arthritis

N041.	Felty's syndrome
X701j	Rheumatoid arthritis with organ / system involvement
N0421	Rheumatoid lung
X701k	Fibrosing alveolitis associated with rheumatoid arthritis
X701l	Rheumatoid vasculitis
X705t	Nailfold rheumatoid vasculitis
X705u	Systemic rheumatoid vasculitis
X705v	Necrotising rheumatoid vasculitis
G5yA.	Rheumatoid carditis
N042z	Rheumatoid arthropathy with visceral or systemic involvement NOS
Nyu10	[X]Rheumatoid arthritis with involvement of other organs or systems
X701m	Rheumatoid arthritis with multisystem involvement
N0408	Rheumatoid arthritis of metacarpophalangeal joint
N040B	Rheumatoid arthritis of hip
N040D	Rheumatoid arthritis of knee
N040C	Rheumatoid arthritis of sacroiliac joint
N040M	Rheumatoid arthritis of interphalangeal joint of toe
N040L	Rheumatoid arthritis of lesser metatarsophalangeal joint
N040G	Rheumatoid arthritis of subtalar joint
N040A	Rheumatoid arthritis of distal interphalangeal joint of finger
N0407	Rheumatoid arthritis of wrist
N0402	Rheumatoid arthritis of shoulder
Xa3gL	Rheumatoid arthritis - multiple joint
N0409	Rheumatoid arthritis of proximal interphalangeal joint of finger
N040F	Rheumatoid arthritis of ankle
N0400	Rheumatoid arthritis of cervical spine
N040E	Rheumatoid arthritis of tibiofibular joint
N040K	Rheumatoid arthritis of first metatarsophalangeal joint
N0401	Other rheumatoid arthritis of spine
N0406	Rheumatoid arthritis of distal radioulnar joint
N040H	Rheumatoid arthritis of talonavicular joint
N040J	Rheumatoid arthritis of other tarsal joint
N040T	Flare of rheumatoid arthritis
Xa3gM	Rheumatoid arthritis - hand joint
Xa3gN	Rheumatoid arthritis - ankle/foot
Xa3gO	Rheumatoid arthritis - other joint
Xa3gP	Rheumatoid arthritis NOS
N0402	Rheumatoid arthritis of shoulder
N0403	Rheumatoid arthritis of sternoclavicular joint
N0404	Rheumatoid arthritis of acromioclavicular joint
N0403	Rheumatoid arthritis of sternoclavicular joint
N0405	Rheumatoid arthritis of elbow

N0406	Rheumatoid arthritis of distal radio-ulnar joint
N0407	Rheumatoid arthritis of wrist
N040C	Rheumatoid arthritis of sacro-iliac joint
N040E	Rheumatoid arthritis of tibio-fibular joint
N040K	Rheumatoid arthritis of 1st metatarsophalangeal joint
N040N	Rheumatoid vasculitis
N040P	Seronegative rheumatoid arthritis
N040Q	Rheumatoid bursitis
N040R	Rheumatoid nodule
N040S	Rheumatoid arthritis - multiple joint
N0455	Juvenile rheumatoid arthritis

8.25 Temporal arteritis Read codes

G755.	Giant cell arteritis
G7550	Cranial arteritis
G7551	Temporal arteritis
G7552	Horton's disease
G755z	Giant cell arteritis NOS
N200.	Giant cell arteritis with polymyalgia rheumatica
Nyu41	[X]Other giant cell arteritis

8.26 Height, weight, BMI Read Codes

Read code	Read term
229..	Height
22A..	Weight
22K..	BMI

8.27 Blood Eosinophil Count Read codes

Read code	Read term
42K..	Eosinophil count
42K1.	Eosinophil count normal
42K2.	Eosinopenia
42K3.	Eosinophil count raised
42KZ.	Eosinophil count NOS
42b9.	Percentage eosinophils
4E32.	Sputum: eosinophilia
D403	Hereditary eosinophilia
D403.	Eosinophilia
D4033	Allergic eosinophilia

Read code	Read term
D4034	Secondary eosinophilia NOS
D403z	Eosinophilia NOS
H583.	Pulmonary eosinophilia
H5831	Tropical eosinophilia
H583z	Pulmonary eosinophilia NOS
J08z	Oral mucosa eosinoph.granuloma
X00l1	Eosinophil non-allergic rhinit
X102G	Asthmatic pulm eosinophilia
X102H	Cryptogenic pulm eosinophilia
X3009	Eosinophilic oesophagitis
X80VM	Eosinophil
Xa0kb	Tropical pulm eosinophilia
Y02Rr	Eosinophil non-allergic rhinit
Y108t	Eosinophilic pneumonia
Y108u	EP - Eosinophilic pneumonia
Y108v	Pulm infiltrate + eosinophilia
Y108w	PIE - Pul infil + eosinophilia
Y108z	Acute eosinophilic pneumonia
Y1090	Simple pulmonary eosinophilia
Y1094	Asthmatic pulm eosinophilia
Y1095	Cryptogenic pulm eosinophilia
Y1096	Chronic eosinophilic pneumonia
Y1097	Crypt eosinophilic pneumonia
Y1098	Chronic pulmonary eosinophilia
Y1099	Tropical pulm eosinophilia
Y20fq	Eosinophilic disorder
Y3017	Eosinophilic oesophagitis
Y80lD	Eosinophil
Ya14p	EP-Acute eosinophil pneumonia
Yaeib	Percentage eosinophil count
YakcK	Eosinophil count - observation

8.28 Spirometry measurement Read codes

Read code	Read term
3396.	Forced vital capacity - FVC
33960	FVC - forced vital capacity normal
33961	FVC - forced vital capacity abnormal
3397.	Forced expiratory volume - FEV
3398.	FEV1/FVC ratio normal
3399.	FEV1/FVC ratio abnormal

Read code	Read term
339a.	FEV1 before bronchodilation
339b.	FEV1 after bronchodilation
339e.	FEV1 pre steroids
339f.	FEV1 post steroids
339h.	FVC after bronchodilation
339j.	FEV1/FVC ratio pre steroids
339k.	FEV1/FVC ratio post steroids
339l.	FEV1/FVC ratio before bronchodilator
339M.	FEV1/FVC ratio
339m.	FEV1/FVC ratio after bronchodilator
339O.	Forced expired volume in 1 second
339O1	Forced expired volume in one second/vital capacity ratio
339P.	Expected FEV1
339R.	FEV1/FVC percent
339s.	Forced vital capacity before bronchodilation
339S.	Percent predicted FEV1
339S0	Percentage predicted FEV1 after bronchodilation
339T.	FEV1/FVC > 70% of predicted
339U.	FEV1/FVC < 70% of predicted
X77Qu	Forced expired volume in 1 second
X77Ra	Forced expired volume in one sec/forced vital capacity ratio
XaCJK	Expected FEV1
XaEFy	FEV1/FVC percent
XaEFz	Percent predicted FEV1
XaIxQ	FEV1 before bronchodilation
XaIxR	FEV1 after bronchodilation
XaIxU	FEV1 pre steroids
XaIxV	FEV1 post steroids
XaJ3K	FVC after bronchodilation
XaJ9B	FEV1/FVC ratio pre steroids
XaJ9C	FEV1/FVC ratio post steroids
XaJ9D	FEV1/FVC ratio before bronchodilator
XaJ9E	FEV1/FVC ratio after bronchodilator
XaPpI	Forced vital capacity before bronchodilation
XaVx3	Percentage predicted FEV1 after bronchodilation

8.29 Peak Expiratory Flow Read codes

Read code	Read term
339..	Respiratory flow rates
3391	Resp. flow rate measured
3392	Resp. flow rate not measured
3393	Resp. flow rate normal
3394	Resp. flow rate abnormal

Read code	Read term
3395	Peak exp. flow rate: PEFR/PFR
339A.	PFR - before bronchodilation
339B.	PFR - after bronchodilation
339C.	PFR - expected
339D.	PFR - best ever
339E.	PFR >80% of predicted
339F.	PFR 60-80% of predicted
339G.	PFR <60% of predicted
339H.	Predicted peak flow
339I.	Expected peak flow rate x 50%
339J.	Optimal peak flow rate
339K.	Expected peak flow rate x 30%
339L.	Expected peak flow rate x 80%
339V.	Recorded/predicted PEFR ratio
339W.	Worst peak flow rate
339X.	Percentage of best ever PEFR
339Y.	Percentage of PEFR variability
339Z.	Respiratory flow rates NOS
339c.	PEFR pre steroids
339d.	PEFR post steroids
339g.	Serial peak expirat flow rate
339n.	Serial PEFR abnormal
339o.	PEFR using EN 13826 device
339p.	Predict PEFR using EN13826 std
339u.	Peak inspiratory flow rate
745C0	Measure peak expirat flow rate

8. ATTACHMENTS

9. SIGNATURES

Authoring Instructions

- *The following signature pages for an Observational Study protocol may be required and further details on who is required to sign can be found in the SOP 8-P102-CV-C Design, Execution, and Reporting of AstraZeneca Sponsored Observational Studies:*
  - *Global Medical Affairs Lead or Global Clinical Lead/Delegate for global studies*
  - *MC Medical Director/Delegate for local studies*
  - *Global Epidemiologist /Local Study Leader*
  - *Optional signature from Biostatistician or Delivery Director*
  - *Always print the names and addresses.*

ASTRAZENECA SIGNATURE(S)

<<Study Description>>

<<This Observational Study Protocol >> <<has/have>> been subjected to an internal AstraZeneca review>>
I agree to the terms of this Study protocol.

AstraZeneca representative

<<Name, title>>	Date (Day Month Year)
<<Email address and telephone number>>	