Study Information

Title	Observational Study of Effectiveness and Safety of Recombinant Zoster Vaccine (Shingrix)® in Moderately-to-Severely Active Ulcerative Colitis (UC) or Rheumatoid Arthritis (RA) Patients Treated with Tofacitinib (Xeljanz)® in Real-World Clinical Care Settings
Protocol number	A3921427
Protocol version identifier	Version 2.1
Date	05 October 2023
EU Post Authorization Study (PAS) register number	EUPAS48998
Active substance	Tofacitinib (ATC code: LD4AA29)
Medicinal product	Xeljanz® (tofacitinib)
Research question and objectives	The research questions are the following: • In patients with moderately to severely active UC or RA receiving ongoing treatment with tofacitinib, what is the incidence rate of HZ in those administered RZV (Shingrix)® compared with those not administered the vaccine? • In patients with moderately to severely active UC or RA receiving ongoing treatment with tofacitinib, does the incidence rate of UC or RA disease flares differ in those who are administered RZV compared with those not administered the vaccine? The primary objective for effectiveness in this study is: • To estimate and compare the incidence rate of HZ among patients with UC or RA being treated with tofacitinib who receive two doses of RZV relative to the incidence rate

	among patients with UC or RA being treated with tofacitinib who do not receive RZV. The secondary objective for effectiveness in this study is: • To estimate and compare the incidence rate of HZ among patients with UC or RA being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with UC or RA being treated with tofacitinib who do not receive RZV. The secondary objectives for safety in this study are: 1. To estimate and compare the incidence rate of UC disease flares among patients with UC being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with UC being treated with tofacitinib who do not receive RZV. 2. To estimate and compare the incidence rate of RA disease flares among patients with RA being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with RA being treated with tofacitinib who do not receive RZV.
Author	Michelle R. Iannacone, PhD Methods Lead, Epidemiologist, Safety Surveillance Research, Pfizer Email: Michelle.Iannacone@pfizer.com

1. TABLE OF CONTENTS

2. LIST OF ABBREVIATIONS

Abbreviation	Definition
AHFS	American Hospital Formulary Service
ATT	Average Treatment Effect in the Treated
COVID-19	Coronavirus Disease 19
CPT®	Current Procedural Terminology
csDMARD	Conventional Synthetic Disease-modifying Antirheumatic Drug
ENCePP	European Medicines Agency, European Network of Centres for Pharmacoepidemiology and
FDA	Food and Drug Administration
HCPCS	Healthcare Common Procedure Coding System
HIV	Human Immunodeficiency Virus
HZ	Herpes Zoster
IBD	Inflammatory Bowel Disease
ICD-10	International Classification of Diseases, 10th Revision
IEC	Independent Ethics Committee
IPTW	Inverse Probability of Treatment Weight
IRB	Institutional Review Board
ISPE	International Society of Pharmacoepidemiology
JAK	Janus Kinase
MA-PD	Medicare Advantage and Medicare Part D
NDC	National Drug Code
ORD	Optum Research Database
PASS	Post-Authorisation Safety Study
PPV	Positive Predictive Value
RA	Rheumatoid Arthritis
RWD	Real-world Data
RWE	Real-world Evidence
RZV	Recombinant Zoster Vaccine
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standardized Difference
SOPs	Standard Operations Procedures
TNF	Tumor Necrosis Factor
UC	Ulcerative Colitis
US	United States

3. RESPONSIBLE PARTIES

Principal Investigator(s) of the Protocol

Name, degree(s)	Job Title	Affiliation	Address
Michelle R. Iannacone, PhD	Methods Lead, Safety Surveillance Research	Pfizer	66 Hudson Blvd E, New York, New York 10001
Claire Pernar, ScD, MPH	Epidemiologist, Epidemiology	Optum	1325 Boylston St, 11th Floor Boston, MA 02215
Andrea K. Chomistek, ScD	Senior Scientist, Epidemiology	Optum	1325 Boylston St, 11th Floor Boston, MA 02215
John Seeger, PharmD, DrPH, FISPE	Chief Scientific Officer, Epidemiology	Optum	1325 Boylston St, 11th Floor Boston, MA 02215

4. ABSTRACT

In Annex 1 as stand-alone document.

5. AMENDMENTS AND UPDATES

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
1	16 May 2023	Throughout the protocol	Updated the order to "effectiveness and safety" from the previous order "safety and effectiveness" Updated study time period units in months to days, such as 365 days instead of 12 months	The order was updated to better reflect the primary and secondary objectives of this study and PMC 3400-6 Time period units in "months" were updated to "days" to be more consistent, as calendar months have varying length in days
		Title Page	Updated objectives to align with changes in protocol Updated protocol author and contact information	Editorial change Study transition for the protocol author
		Section 2	Updated to include new abbreviations	Editorial change
		Section 3	Updated contact information for a principal investigator of the protocol	Study transition for the principal investigator
		Section 4	Revised version, date, and author Updated objectives, eligibility criteria, cohorts, and follow-up to reflect the 2-dose analysis as the primary objective	Editorial change and study transition The abstract was updated based on updates in the protocol, which was updated in response to the FDA feedback (dated 03 February 2023) on protocol version 1.0
		Section 6	Updated milestone dates	Project timelines have changed due to this protocol amendment in response to the FDA feedback (dated 03 February 2023) on protocol version 1.0

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
		Section 7	Added text and citation on the recommended dosing schedule of RZV	Editorial changes to add the dosing schedule in the background section
		Section 8	Changed study objectives such that assessment of the 2-dose regimen is the primary objective.	This change was made in response to request by the FDA in their feedback on protocol version 1.0.
		Section 9.1	Addition of cohorts to correspond to revised study objectives. Extension of study period end date from 31 December 2022 to 31 July 2023 (or most recent available data at the time the data are extracted).	This change was made in response to request by the FDA in their feedback on protocol version 1.0, Study period extended due to later start of data collection.
		Section 9.2	Updated the study population, specifically the eligibility criteria (Section 9.2.1 and 9.2.2), exposure and comparator cohort definitions (Section 9.2.3.2), baseline period definition (Section 9.2.4), and follow-up period definitions (Section 9.2.5) to correspond to revised study objectives.	This change was made in response to request by the FDA in their feedback on protocol version 1.0 (dated 03 February 2023), which requested the 2-dose RZV analysis to be the primary objective.
		Section 9.3.4	Updated definitions to distinguish RZV doses using claims codes	This change was made in response to request by the FDA in their feedback on protocol version 1.0.
		Section 9.3.5.2	Removed biologics (TNF and non-TNF) from the list of medications considered as part of the definition for UC disease flare	Upon further review of the literature, most studies using claim-based indicators to capture UC or RA disease flares did not include biologics as part of their algorithms [18,20,23]. Only one study included biologic as a predictor of UC disease flare[19], but when evaluated as a single indicator, biologic was not a statistically significant positive predictor of UC flare. Thus, biologics

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
				were removed from the medications considered for UC disease flare in the secondary objective, and also to be consistent with the definition for RA disease flare. Biologics will be explored as part of the disease flare definition in sensitivity analysis (Section 9.7.4)
		Section 9.4.2	Updated abbreviated name for database to full name	Editorial change
		Section 9.5	Updated study size using the most recently available data	Updated preliminary patient counts based on the most recent data
		Section 9.7	Updated data analysis (propensity score modeling in Section 9.7.1, IPTW in Section 9.7.2) to correspond to revised study objectives including separate propensity score models for 2-dose and ≥1 dose analyses and subgroup analyses. Updated text in Section 9.7.3 to reflect the 2-dose analysis as the primary analysis	This change was made in response to request by the FDA in their feedback on protocol version 1.0.
		Section 9.7.4	Added sensitivity analyses to 1) examine recent tofacitinib users (discontinuation within specified time period) in addition to current tofacitinib users, and 2) explore alternative definitions of disease flare, including more expansive definitions that consider other medications of interest, such as biologics and other JAK inhibitors	Sensitivity analysis on recent tofacitinib users was added to evaluate across a range of real-world use patterns and address the potential for extended immunosuppressant effects of tofacitinib following discontinuation. Sensitivity analysis on alternative definitions of disease flare was added to evaluate potential misclassification of outcome.
		Section 9.9	Added study limitation regarding 1) potential misclassification of RZV dose, and 2) potential misclassification of disease flare	Limitations were added to address study limitations when using claims data

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
2	05 October 2023	Section 9.2.2	Updated exclusion criterion to clarify that patients with a diagnosis code for HZ infection on the cohort entry date (Day 0) will not be excluded from the study	This clarification was made to align the exclusion criterion with Figure 2(a) in response to the FDA feedback on protocol version 2.0 (letter dated 30 June 2023).
		Section 9.3.5.1	Added text to clarify the operational definition of HZ infection	This update was made to provide justification and clarity in response to the FDA feedback on protocol version 2.0 (letter dated 30 June 2023).
		Section 9.3.6.4	Added a variable for number of UC/RA treatments during the baseline period to the list of covariates	This variable was added to enhance capture of disease severity.

6. MILESTONES

Milestone	Planned date
Start of data collection	02 January 2024
End of data collection	14 September 2024
Registration in the EU PAS register	Pending (prior to start of data collection)
Final study report*	14 September 2025

*Anticipated to include data from 20 October 2017 to 31 July 2023 (or most recent available data at the time the data are extracted)

7. RATIONALE AND BACKGROUND

Tofacitinib (Xeljanz®, Pfizer Inc., New York, NY) is an oral Janus kinase (JAK) inhibitor with multiple indications, including for individuals with moderately to severely active ulcerative colitis (UC) or rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. UC, a type of inflammatory bowel disease (IBD), is an autoimmune condition involving chronic inflammation of the mucosa of the rectum and colon, clinically characterized by bloody diarrhea and abdominal pain.[1] Rheumatoid arthritis (RA) is an autoimmune condition involving chronic localized and systemic inflammation, with inflammation of the joints leading to erosion or destruction of joint structures, affecting function, and leading to progressive disability.[2] Patients who have UC or RA are at increased risk of infections, including herpes zoster (HZ), due to the underlying autoimmune condition, and also as a consequence of treatment with immunosuppressant therapies.[3,4] Increased rates of HZ have been observed in patients treated with tofacitinib compared to patients receiving placebo.[5,6] Consequently, HZ is among the infections included in the Warnings section in the prescribing information for tofacitinib.[7]

Shingrix®, a recombinant zoster vaccine (RZV), was approved in the United States (US) in October 2017 for the prevention of HZ infection in adults 50 years and older who are immunocompetent. It was subsequently approved (July 2021) for use in adults 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy. In adults with weakened immune systems, RZV was between 68% and 91% effective in preventing HZ, depending on their underlying immunocompromising condition.[8] RZV is a 2 dose vaccine; it is recommended that the second RZV dose be given 2 – 6 months after the first, or 1 – 2 months after the first if needed among people with weakened immune systems.[9]

Given the immunosuppressive effects of tofacitinib, which provide a foundation for clinical benefit in treating patients with UC or RA, there is concern that RZV administered to patients receiving ongoing treatment with tofacitinib may be less effective in preventing HZ. Additionally, as RZV is an adjuvanted vaccine, there has been question as to whether it could induce flares in patients with UC or RA.[10,11] Given these concerns along with the recently

expanded indication for use of RZV, a study to assess the real-world effectiveness and safety of RZV in this population is to be conducted. This is a post-approval effectiveness and safety study in which Optum proposes to utilize real-world data (RWD) in accordance with US Food and Drug Administration (FDA) guidance for industry about the use of real-world evidence (RWE) to help support post-approval study requirements.[12,13] This study presents a valuable opportunity to use RWD since RZV is approved for use in immunocompromised adults 18 years and older and is the current standard of care.[8]

This non-interventional study is designated as a Post-Authorisation Safety Study (PASS) and is a post-marketing commitment to the United States (US) (FDA).

8. RESEARCH QUESTION AND OBJECTIVES

The research questions are the following:

1. In patients with moderately to severely active UC or RA receiving ongoing treatment with tofacitinib, what is the incidence rate of HZ in those administered RZV (Shingrix®) compared with those not administered the vaccine?

2. In patients with moderately to severely active UC or RA receiving ongoing treatment with tofacitinib, does the incidence rate of UC or RA disease flares differ in those who are administered RZV compared with those not administered the vaccine?

The primary objective for effectiveness in this study is:

- To estimate and compare the incidence rate of HZ among patients with UC or RA being treated with tofacitinib who receive two doses of RZV (between 1 and 6 months apart as specified in Section 9.2.3.2.1.1) relative to the incidence rate among patients with UC or RA being treated with tofacitinib who do not receive RZV.

The secondary objective for effectiveness in this study is:

- To estimate and compare the incidence rate of HZ among patients with UC or RA being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with UC or RA being treated with tofacitinib who do not receive RZV.

The secondary objectives for safety in this study are

1. To estimate and compare the incidence rate of UC disease flares among patients with UC being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with UC being treated with tofacitinib who do not receive RZV.

2. To estimate and compare the incidence rate of RA disease flares among patients with RA being treated with tofacitinib who receive at least one dose of RZV relative to the incidence rate among patients with RA being treated with tofacitinib who do not receive RZV.

9. RESEARCH METHODS

9.1. Study Design

This is a non-interventional observational cohort study to evaluate the effectiveness and safety of RZV in real-world patients with UC or RA receiving ongoing treatment with tofacitinib. As claims data typically have data lags due to the delay between the occurrence of a health service, claim adjudication, until data availability, adult patients 18 years and older with UC or RA treated with tofacitinib between 20 October 2017 (the date of RZV approval in the US) and 31 July 2023 (or most recent available data at the time the data are extracted) will be identified.

Based on diagnosis of UC or RA and receipt of RZV, patients who are current users of tofacitinib (defined in Section 9.2.3.1) will be classified into the following 8 exposure cohorts, as illustrated by Figure 1.

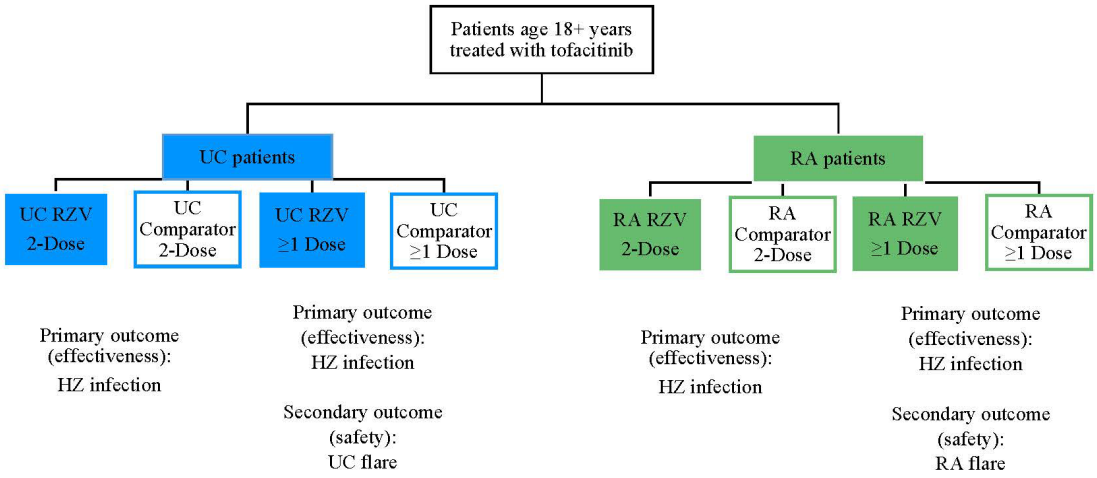
Cohorts for the primary objective (effectiveness):

1. UC RZV 2-Dose: UC patients who receive two doses of RZV;
2. UC Comparator 2-Dose: UC patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the UC RZV 2-Dose cohort;
3. RA RZV 2-Dose: RA patients who receive two doses of RZV;
4. RA Comparator 2-Dose: RA patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the RA RZV 2-Dose cohort;

Cohorts for the secondary objectives (effectiveness and safety):

5. UC RZV ≥1 Dose: UC patients who receive at least one dose of RZV;
6. UC Comparator ≥1 Dose: UC patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the UC RZV ≥1 Dose cohort;
7. RA RZV ≥1 Dose: RA patients who receive at least one dose of RZV; and
8. RA Comparator ≥1 Dose: RA patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the RA RZV ≥1 Dose cohort.

Figure 1. Study Design



To assess the effectiveness of RZV among patients treated with tofacitinib, the primary outcome for this study is the occurrence of new HZ infection. Occurrences of new HZ infection will be identified by the presence of a diagnostic code in claims for HZ infection after the second dose of RZV in the primary objective and after the first dose of RZV in the secondary objective. To assess the safety of RZV among patients treated with tofacitinib, the secondary outcome for this study is disease flare after the first dose of RZV: UC flare within the UC cohorts and RA flare within the RA cohorts. Occurrences of disease flare will be defined based on claims-based indicators and informed by review of the published literature.

Propensity scores that discriminate between receipt and non-receipt of RZV will be created from a wide variety of baseline demographic, comorbidity, disease severity (based on proxies for disease severity, such as treatment with advanced therapy), and comedication indicators, as well as risk factors for HZ. The propensity scores will be used to calculate inverse probability of treatment weights (IPTWs) to adjust for potential confounding in the comparative analysis. The main analysis for this project will estimate the incidence of the primary and secondary outcomes within the weighted cohorts, comparing those with RZV receipt to those without RZV receipt, yielding estimates of RZV effectiveness (primary and secondary outcomes) and safety (secondary outcomes) in those treated with tofacitinib. The main comparison will be among the subgroup of patients whose treatment with tofacitinib overlaps with both doses of RZV relative to patients treated with tofacitinib who do not receive RZV, as sample size allows. All analyses will be performed separately within the UC and RA cohorts.

9.2. Setting

The source population will consist of adult patients 18 years and older treated with tofacitinib with moderately to severely active UC or RA between 20 October 2017 (the date

of RZV approval in the US) and 31 July 2023 (or most recent available data at the time the data are extracted). Severity of UC and RA will not be measured directly; rather, it will be assumed based on the indications for tofacitinib treatment.[7] Exposure to tofacitinib will be identified as described in Section 9.2.3.1.

9.2.1. Inclusion Criteria

Patients must meet all of the following inclusion criteria at the time of cohort entry (defined as the second qualifying RZV administration date in Section 9.2.3.2.1.1 for the RZV 2-Dose analysis, and as the first qualifying RZV administration date in Section 9.2.3.2.2.1 for the RZV ≥1 Dose analysis) to be eligible for inclusion in the study:

1. Aged 18 years of age or older;

2. Have complete medical coverage and pharmacy benefits (ie, eligible to receive complete reimbursement, minus applicable co-pays, for physician, hospital, and prescription drug services) and have at least 365 days of continuous health plan enrollment prior to and including cohort entry date;

    - Patients in the RZV 2-Dose analysis will also be required to have complete medical coverage and pharmacy benefits and continuous health plan enrollment during the 28 days after cohort entry date, as the follow up time will be assessed from day 29 after cohort entry date (Section 9.2.5.1);

3. Identified as a current user of tofacitinib; and

4. Have a diagnosis of UC or RA in the 365 days prior to and including the cohort entry date.

9.2.2. Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Receipt of RZV (comparator cohorts only in the RZV 2-Dose analysis) during the 365 days prior to cohort entry, excluding the cohort entry date;

2. Diagnosis of HZ infection in the 365 days prior to cohort entry, excluding the cohort entry date;

    - Presence of a diagnosis code for HZ infection on the same date as RZV receipt (Dose 1 or Dose 2) will not be cause for exclusion from the study due to the administrative claims process;

3. Receipt of a solid organ transplant or hematopoietic stem cell transplant during the 365 days prior to cohort entry, excluding the cohort entry date;

4. In addition, patients with any of the following claims-based indicators of disease flare during the 91 days prior to cohort entry (as described in Section 9.2.3.2.1 for the RZV 2-Dose analysis, and in Section 9.2.3.2.2 for RZV ≥1 Dose analysis) will not be included in the study:

    - Emergency room visit or hospitalization with UC as primary diagnosis (UC cohorts);
    - UC-related surgery (ie, colectomy, proctocolectomy) (UC cohorts); and
    - Emergency room visit or hospitalization with RA as primary diagnosis (RA cohorts).

In addition, patients meeting any of the following criteria will not be included in the RZV 2- Dose analysis:

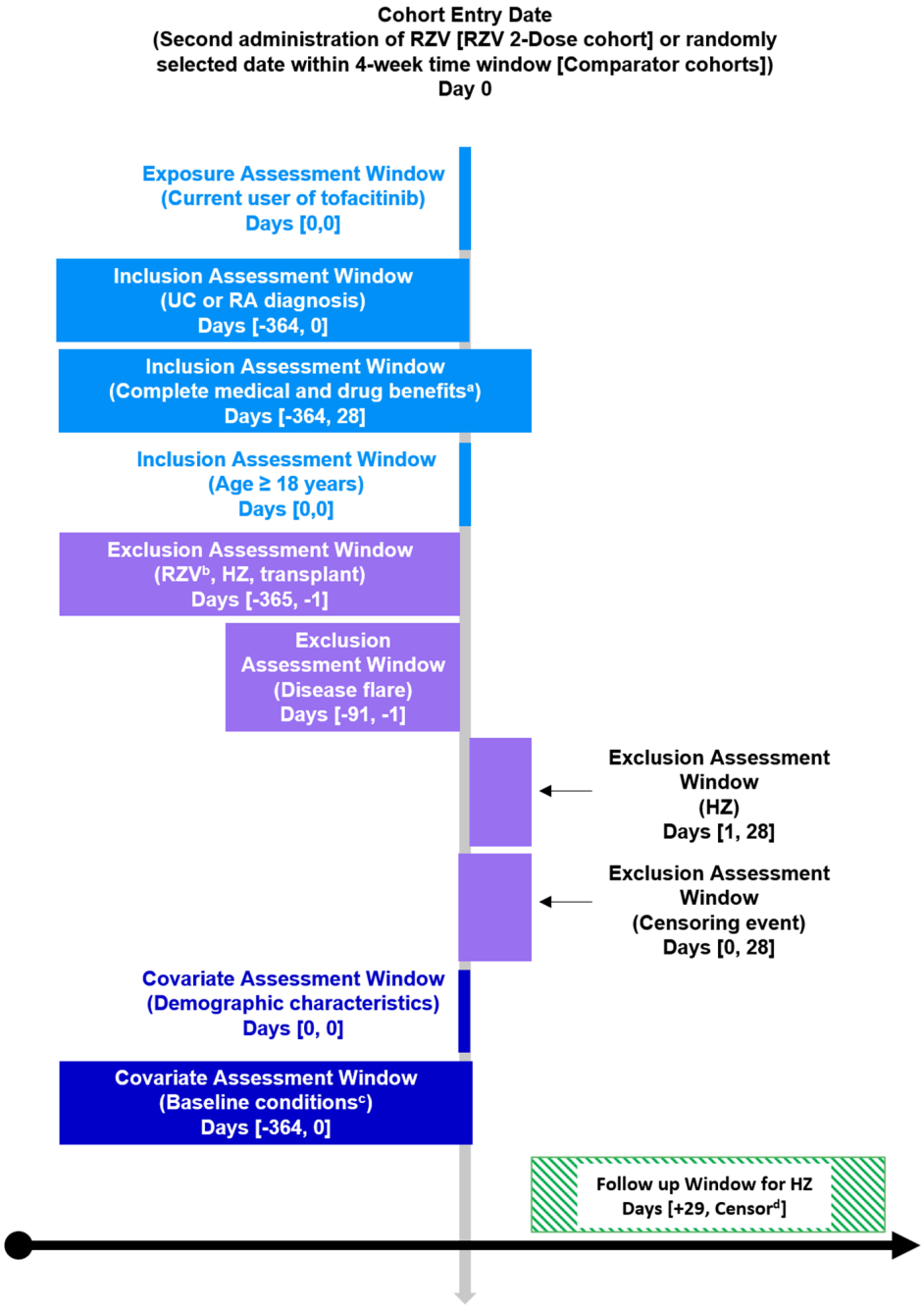
5. Diagnosis of HZ infection within 28 days after but not including the cohort entry date (ie, Days [1,28]), as the follow up time will be assessed from day 29 after cohort entry date (Section 9.2.5.1); and

6. Occurrence of any censoring event (ie, disenrollment from health plan, death, end of the study period, or receipt of RZV) within 28 days after cohort entry date (Section 9.2.5.1).

Figure 2 summarizes the schematic for assessing patient eligibility, as well as assessment of covariates and outcomes, for (a) the RZV 2-Dose analysis and (b) the RZV ≥1 Dose analysis, with details outlined in the subsequent sections.

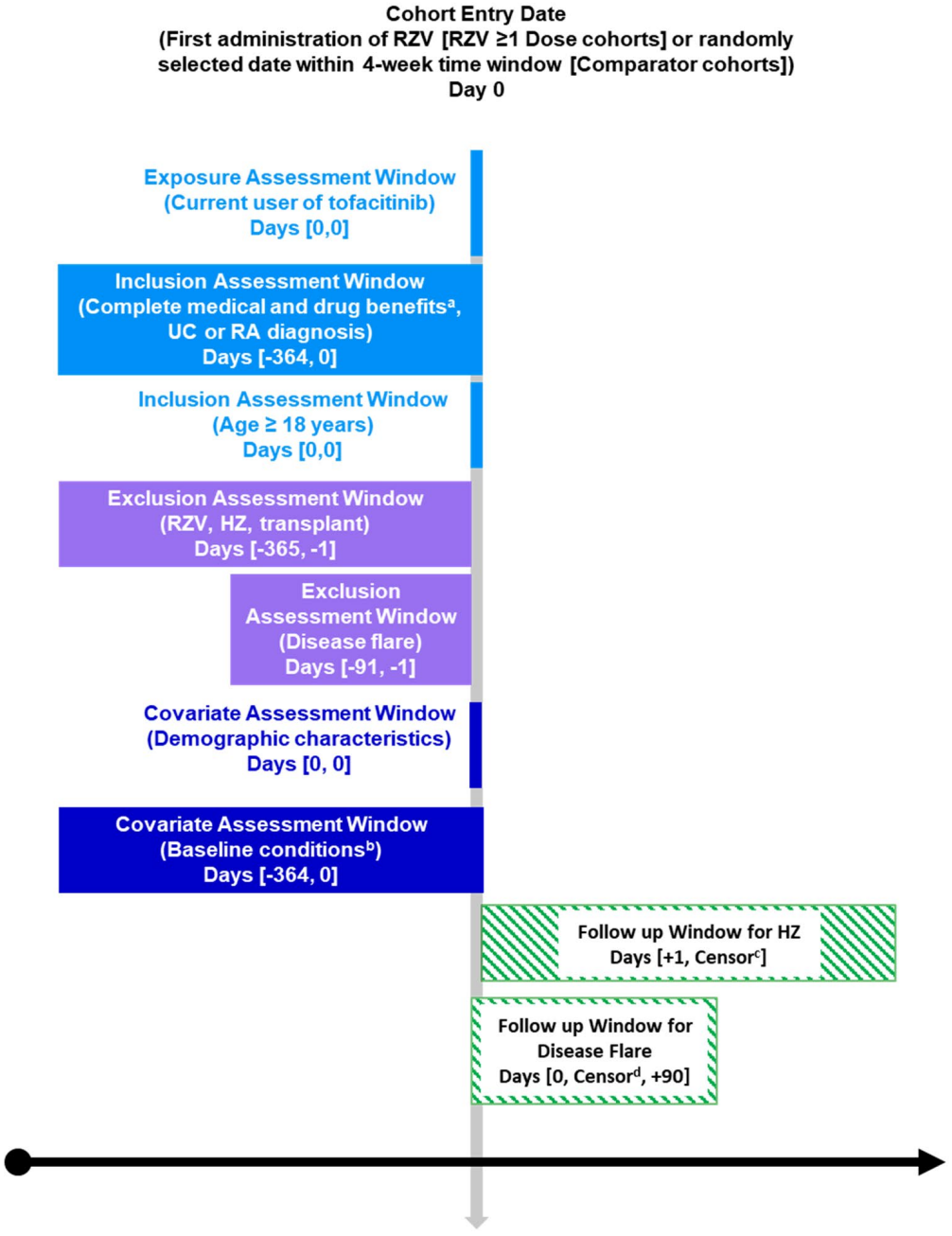
Figure 2. Schematic for Assessing Eligibility, Covariates, and Outcomes of RZV Initiators and Comparators in (a) RZV 2-Dose Analysis and (b) RZV ≥1 Dose Analysis

(a)



a. Up to 32 day gaps in medical or pharmacy enrollment allowed
b. Receipt of RZV exclusion applied to Comparator cohorts only
c. Baseline conditions included: healthcare utilization, comorbid conditions, and treatment history
d. Earliest of: outcome of interest (HZ), disenrollment, death, end of the study period, or receipt of RZV (comparator cohorts only)

(b)



a. Up to 32 day gaps in medical or pharmacy enrollment allowed
b. Baseline conditions included: healthcare utilization, comorbid conditions, and treatment history
c. Earliest of: outcome of interest (HZ), disenrollment, death, end of the study period, or receipt of RZV (comparator cohorts only)
d. Earliest of: outcome of interest (disease flare), disenrollment, death, end of the study period, receipt of RZV (comparator cohorts only), or 90 days of follow-up

9.2.3. Study Population

9.2.3.1. Identification of Current Tofacitinib Users

As this study aims to assess the effectiveness and safety of RZV among patients receiving ongoing treatment with tofacitinib, we will identify current users of tofacitinib rather than new users or initiators as the source population to identify patients with and without RZV vaccine.

A patient will be considered to be a current user of tofacitinib if they have a tofacitinib on-treatment period on or after 20 October 2017. The date of tofacitinib dispensing will serve as the first day of the on-treatment period. The duration of the on-treatment period will be defined by the days' supply for the dispensing plus a grace period of 30 days to account for non-adherence. A patient will continue to be considered a current user if the time between the current and subsequent dispensing of tofacitinib is less than or equal to the days' supply plus 30 days. Otherwise, the on-treatment period will cease at the end of the 30-day grace period, and the patient will no longer be considered a current user of tofacitinib. (It should be noted that discontinuation of tofacitinib is not a censoring criterion. Patients who were previously included in one of the exposure cohorts while they were on-treatment for tofacitinib will continued to be followed if their tofacitinib on-treatment period ends.) If the patient restarts treatment with tofacitinib (ie, has another on-treatment period) after the end of a previous on-treatment period, the patient may be included in the study if they continue to meet the other eligibility criteria.

If there are consecutive dispensings of tofacitinib with overlapping days' supply, the duration of the on-treatment period will be the sum of the days' supply from each dispensing plus 30 days if the dose of tofacitinib is the same for both dispensings, as it is likely that this represents an early refill. However, if the dose of tofacitinib is different for the subsequent dispensing, the end date for the earlier dispensing will be set to the day prior to the dispensing date of the subsequent dispensing when calculating the duration of the on-treatment period.

Once patients who are current users of tofacitinib on or after 20 October 2017 have been identified, the source population will be restricted to those who are 18 years and older and have a diagnosis of UC or RA on or after 20 October 2016.

9.2.3.2. Exposure Cohorts

9.2.3.2.1. RZV 2-Dose Analysis

The RZV 2-dose analysis will be used to assess the primary objective for effectiveness.

Using UC patients as an example, patients who are current users of tofacitinib will be identified into the following 2 cohorts, based on receipt of RZV, as illustrated in Figure 1:

1. UC RZV 2-Dose: UC patients who receive two doses of RZV; and

2. UC Comparator 2-Dose: UC patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the UC RZV 2-Dose cohort.

Exposure cohorts among patients with RA will be identified using the same framework.

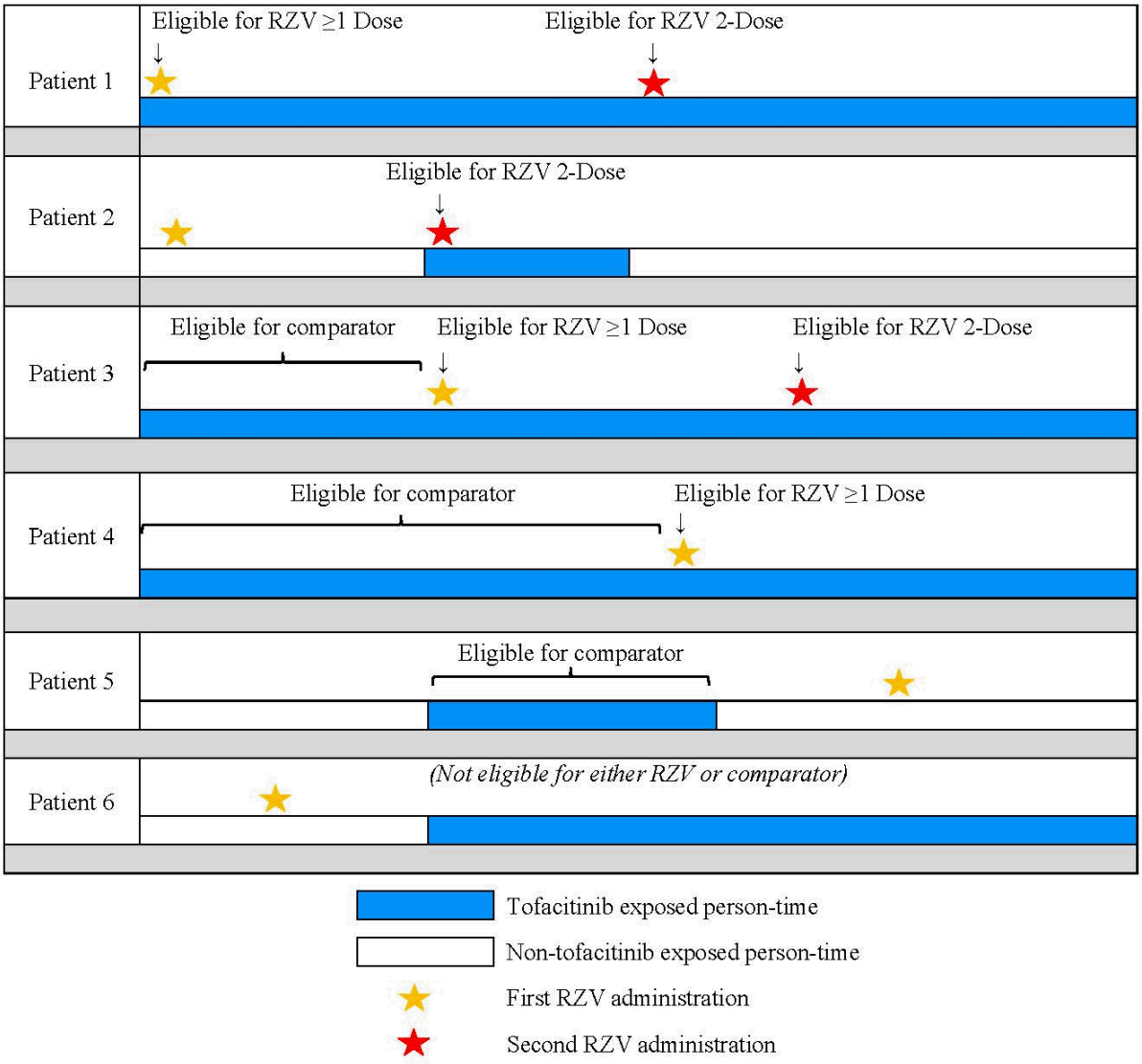
9.2.3.2.1.1. RZV 2-Dose Cohorts

Starting at the beginning of the study period (20 October 2017), Optum will identify the RZV 2-Dose cohorts by searching the pharmacy and medical claims records for RZV administrations among patients who are current users of tofacitinib (as defined in Section 9.2.3.1). Specifically, administrations of RZV that occur during tofacitinib on-treatment periods will be identified, as illustrated in Figure 3. A RZV administration will be defined as a second dose if a separate RZV administration is observed in the previous 1 to 6 months.[9] Exposure to RZV will be identified as described in Section 9.3.4.

The RZV 2-Dose cohorts (UC or RA) will include patients who receive a second dose of RZV with the second dose occurring during a tofacitinib on-treatment period on or after the study initiation date. In the RZV 2-Dose cohorts, *the date of cohort entry will be set as the date of the second administration of RZV*. Additionally, to be eligible for the study, patients will have to fulfill additional criteria, as described in Sections 9.2.1 and 9.2.2.

While current tofacitinib exposure will be required at cohort entry (ie, receipt of second dose in the RZV 2-Dose cohort), the first dose of RZV will not be required to occur during a tofacitinib on-treatment period to be eligible for the RZV 2-Dose cohort. As shown in Figure 3, both example Patient 1 and Patient 2 are eligible for the RZV 2-Dose cohort at the time of receipt of the second RZV dose. Nonetheless, the main comparison will be the subgroup of patients whose treatment with tofacitinib overlaps with both doses of RZV relative to patients treated with tofacitinib who do not receive RZV (Section 9.7.3.1)

Figure 3. Examples of Patients Eligible for the RZV Cohort and/or Comparator Cohort



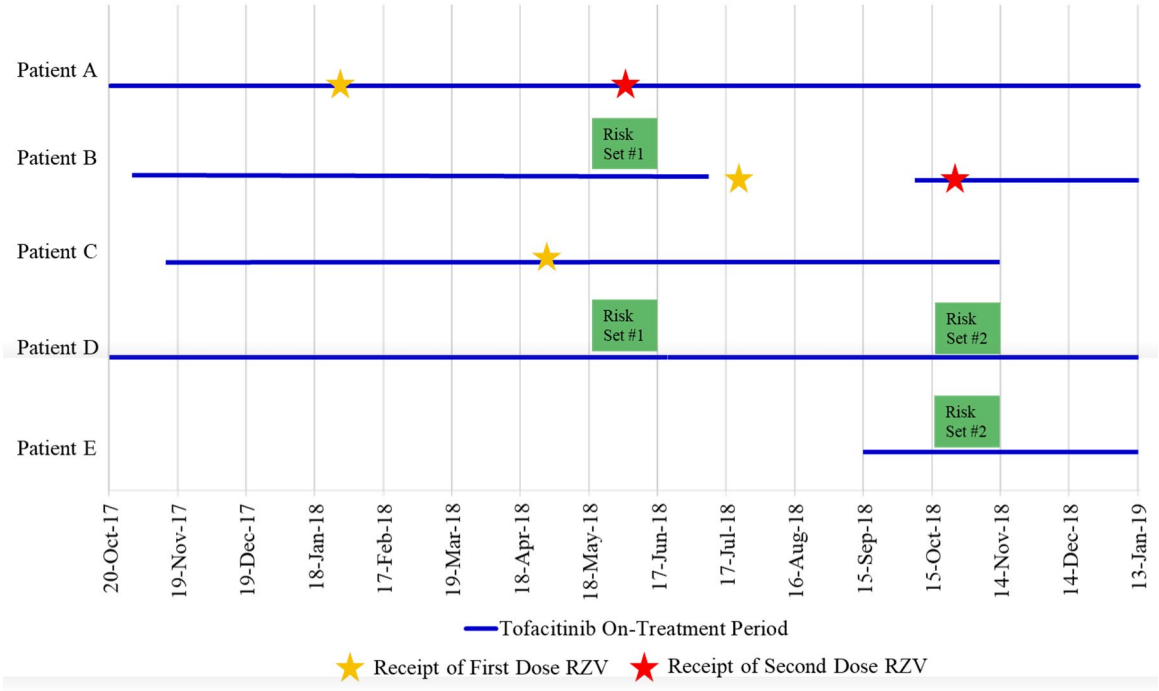
9.2.3.2.1.2. Comparator 2-Dose Cohorts

In a similar fashion to the identification of the RZV 2-Dose cohorts, Optum will identify a cohort of patients without exposure to RZV among patients who are current users of tofacitinib. To minimize the immortal time bias that may be introduced when exposure is defined based on information accrued during follow-up,[14] these patients will be randomly drawn from time-matched vaccination risk sets that are defined as sequential 4-week windows during which they were eligible for inclusion in the RZV cohorts, but without any RZV exposure during the window. Matching within this narrow caliper of calendar time limits the potential immortal time introduced by using future information (ie, lack of RZV receipt) to classify patients at the time of cohort entry. A cohort entry date will be randomly selected from this time window. In addition, other factors, such as duration of tofacitinib use, will be considered for matching upon feasibility, which will be described in the statistical analysis plan (SAP).

To construct the vaccination risk sets, separate 4-week windows will be created, starting on the study initiation date (20 October 2017) through the end of the study period. Among patients who are current tofacitinib users within a given 4-week window, patients without any RZV exposure who meet the study inclusion criteria (Section 9.2.1) and exclusion criteria (Section 9.2.2) at the beginning of the 4-week window will be identified. These patients will be eligible to be sampled as comparator patients for each RZV initiator identified with receipt of a second RZV dose during the same 4-week window. For example, as illustrated in Figure 4, patient A at the time of second RZV dose was eligible to be matched to comparator patient B and D during risk set #1, and similarly, patient B at the time of second RZV dose was eligible to be matched to comparator patient D and E during risk set #2.

Up to 2 comparators for each RZV initiator will be selected, matched on data source (ie, the Optum Research Database [ORD] or the Optum Medicare Advantage and Medicare Part D [MA-PD] Database) and other factors considered upon feasibility. Patients will be sampled with replacement. This process will be repeated for each 4-week window during the study period; as such, it is possible that a patient could be sampled as a comparator multiple times during the study. If patients are selected more than once into the study, it will be accounted for in the statistical analysis (Section 9.7.3).

Figure 4. Example of Time-Matched Vaccination Risk Sets in the RZV 2-Dose Analysis



If a patient selected for the comparator cohort subsequently receives RZV, their follow-up time within the comparator cohort will be censored upon the date of first administration of RZV. The patient may then be included in the RZV cohorts if they still meet all eligibility criteria. Consequently, patients are eligible to contribute person-time to the RZV cohort, the comparator cohort, or both the comparator cohort and (if subsequently vaccinated) the RZV cohort. Once a person contributes person-time to the RZV cohort, they are no longer eligible to contribute to the comparator cohort.

Patients with and without RZV exposure will be included in the UC RZV cohort and UC Comparator cohort, respectively, if they have at least one medical claim with a diagnosis of UC (International Classification of Diseases, 10th revision [ICD-10] code: K51*) in any position in the 365 days prior to and including their cohort entry date. Similarly, patients with and without RZV exposure will be included in the RA RZV cohort and RA Comparator cohort, respectively, if they have at least one medical claim with a diagnosis of RA (ICD-10 code: M05*) in any position in the 365 days prior to and including their cohort entry date. In addition, M06* (other rheumatoid arthritis) will also be used, except M06.1 (adult-onset Still's disease) and M06.4 (inflammatory polyarthropathy). If a patient has claims with both UC and RA diagnoses in the 365 days prior to cohort entry, the claim closest to the cohort entry date will be used for cohort assignment.

9.2.3.2.2. RZV ≥1 Dose Analysis

The RZV ≥1 dose analysis will be used to assess the secondary objectives for effectiveness and safety.

Separate cohorts will be created to address the secondary objectives for effectiveness and safety comparing patients who receive at least one dose of RZV to patients who do not receive of RZV. Using patients with UC as an example and similarly to the RZV 2-Dose analysis, patients who are current users of tofacitinib will be identified into the following 2 cohorts, based on receipt of RZV, as illustrated in Figure 1:

1. UC RZV ≥1 Dose: UC patients who receive at least one dose of RZV; and
2. UC Comparator ≥1 Dose: UC patients who do not receive RZV and are time-matched (within a 4-week window) to patients in the UC RZV ≥1 Dose cohort.

Exposure cohorts among patients with RA will be identified using the same framework.

9.2.3.2.2.1. RZV ≥1 Dose Cohorts

Starting at the beginning of the study period (20 October 2017), Optum will identify the RZV ≥1 Dose cohorts by searching the pharmacy and medical claims records for RZV administrations among patients who are current users of tofacitinib (as defined in Section 9.2.3.1). Specifically, administrations of RZV that occur during tofacitinib on-treatment periods will be identified, as illustrated in Figure 3. Exposure to RZV will be identified as described in Section 9.3.4.

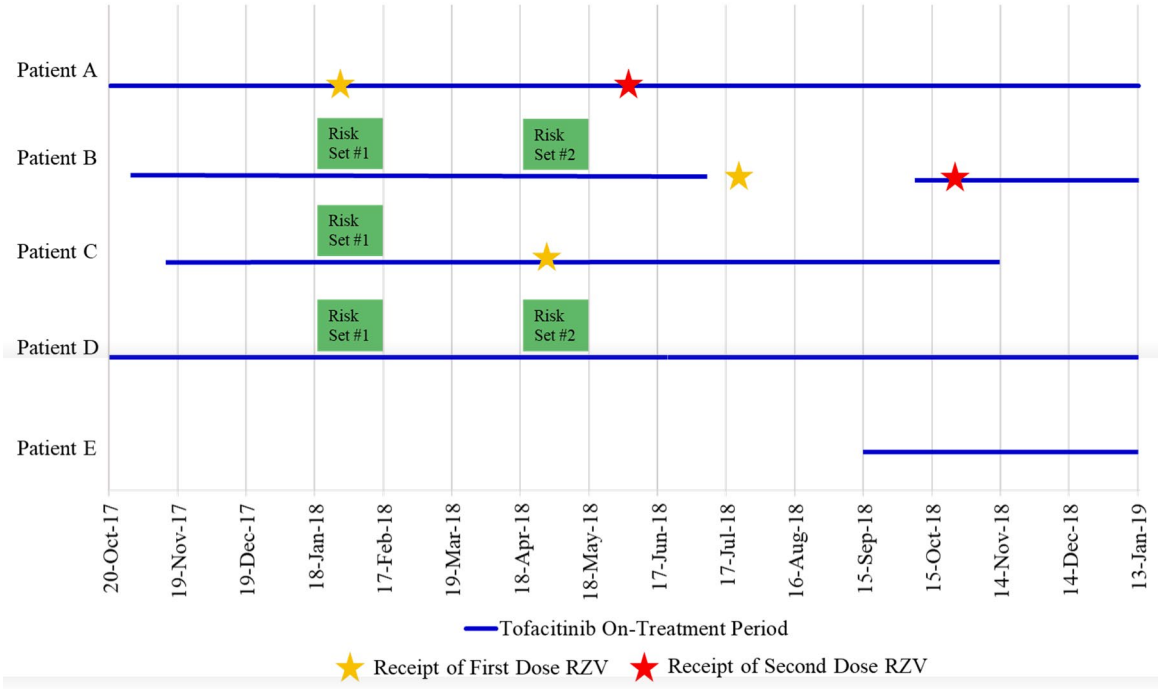
In the RZV ≥1 Dose cohorts (UC or RA), *the date of cohort entry will be set as the date of the first administration of RZV* during a tofacitinib on-treatment period on or after the study initiation date, with no administration of RZV in the prior 365 days. Additionally, to be eligible for the study, RZV initiators will have to fulfill additional criteria, as described in Section 9.2.1 and 9.2.2 and shown in Figure 2(b).

9.2.3.2.2.2. Comparator ≥1 Dose Cohorts

Optum will identify patients in the UC and RA Comparator ≥1 Dose cohorts in a similar fashion used to identify UC and RA Comparator 2-Dose cohorts, as described in Section 9.2.3.2.1.2. These patients will be randomly drawn from time-matched vaccination risk sets that are defined as sequential 4-week windows during which they were eligible for inclusion in the RZV ≥1 Dose cohorts, but without any RZV exposure during the window. These patients will be eligible to be sampled as comparator patients for each RZV initiator identified with receipt of a first RZV dose during the same 4-week window. For example, as illustrated in Figure 5, patient A at the time of first RZV dose was eligible to be matched to comparator patient B, C, and D during risk set #1, and similarly, patient C at the time of first RZV dose was eligible to be matched to comparator patient B and D during risk set #2. A cohort entry date will be randomly selected from within this time window. Up to 2

comparators for each RZV initiator will be selected, matched on data source (ie, the ORD or the MA-PD Database) and other factors considered upon feasibility.

Figure 5. Example of Time-Matched Vaccination Risk Sets in the RZV ≥1 Dose Analysis



9.2.4. Baseline Period

For each of the study cohorts, the baseline period will be defined as the 365 days prior to and including the cohort entry date. Recognizing that a narrower (for time-varying covariates, etc.) or broader (for chronic conditions, etc.) window of assessment may better capture select patient attributes of interest, select covariates may be assessed using alternate time period(s). Patients selected into more than one cohort (eg, RZV ≥1 Dose and RZV 2-Dose cohorts) will have separate baseline periods corresponding to each date of cohort entry.

9.2.5. Follow-up

9.2.5.1. RZV 2-Dose Analysis

In the 2-dose analysis, the occurrence of the primary outcome, HZ, for each cohort member will be assessed from day 29 after cohort entry until the first occurrence of HZ, disenrollment from the health plan, death, end of the study period, or receipt of RZV (ie, receipt of a third dose for the RZV cohorts or a first dose for the UC comparator and RA comparator cohorts only). The start of follow-up for HZ will begin on day 29 to allow for development of an immune response following receipt of the second RZV dose.[15]

9.2.5.2. RZV ≥1 Dose Analysis

In the ≥1 dose analysis, the occurrence of the primary outcome, HZ, for each cohort member will be assessed from the day after cohort entry until the first occurrence of HZ, disenrollment from the health plan, death, end of the study period, or receipt of RZV (patients in the UC comparator and RA comparator cohorts only). As patients may receive a diagnosis code for HZ on the date of RZV receipt, HZ diagnoses on the cohort entry date will not be counted as outcomes.

The occurrence of the secondary outcome, disease flare, will be assessed from the cohort entry date until the first occurrence of disease flare, disenrollment from the health plan, death, end of the study period, receipt of RZV (patients in the UC comparator and RA comparator cohorts only), or 90 days after cohort entry.

Primary and secondary outcomes will be assessed independently of one another; occurrence of the primary or secondary outcome will not lead to censoring for the other outcome. Furthermore, HZ and disease flare outcomes will be assessed in the RZV 2-Dose and Comparator 2-Dose cohorts independently of the RZV ≥1 Dose and Comparator ≥1 Dose cohorts. Onset of HZ that occurs during person-time between the first and second RZV doses will be attributed to the RZV or Comparator ≥1 Dose cohorts, and not the RZV or Comparator 2-Dose cohorts (see Section 9.2.2). Tofacitinib discontinuation will not censor follow-up for either the primary or the secondary outcome.

9.3. Variables

9.3.1. Exposure to Tofacitinib

Tofacitinib treatment will be identified through the presence of National Drug Codes (NDCs) on pharmacy claims. In addition to dispensings of tofacitinib, other variables, such as duration of treatment and dose, will also be assessed as detailed in Section 9.2.3.1. Tofacitinib will be assessed through the presence of the following NDCs in pharmacy claims:

- NDC 00069050114 XELJANZ XR 11 mg extended-release tablet;
- NDC 00069050130 XELJANZ XR 11 mg extended-release tablet;
- NDC 00069050230 XELJANZ XR 22 mg extended-release tablet;
- NDC 00069100101 XELJANZ 5 mg tablet;
- NDC 00069100201 XELJANZ 10 mg tablet;
- NDC 00069102901 XELJANZ 1 MG/ML oral solution;
- NDC 00069102902 XELJANZ 1 MG/ML oral solution.

9.3.2. Ulcerative Colitis

Patients will be eligible for the UC cohorts if, within the 365 days prior to and including their cohort entry date, they have at least one medical claim with a diagnosis of UC (ICD-10 code: K51*, Ulcerative colitis) in any position.

9.3.3. Rheumatoid Arthritis

Patients will be eligible for the RA cohorts if, within the 365 days prior to and including their cohort entry date, they have at least one medical claim with a diagnosis of RA (ICD-10 code: M05*, Rheumatoid arthritis with rheumatoid factor) in any position. In addition, M06* (other rheumatoid arthritis) will also be used, except M06.1 (adult-onset Still's disease) and M06.4 (inflammatory polyarthropathy).

9.3.4. Exposure to RZV

RZV will be identified using a comprehensive list of codes denoting RZV, including Current Procedural Terminology® (CPT) [1] codes on medical claims or NDCs on pharmacy claims. This approach was used in a previous claims-based study of RZV and is expected to be a valid measure of exposure since the cost of RZV is covered by commercial insurance.[15]

RZV will be assessed through the presence of the following procedure codes or NDCs in medical or pharmacy claims:

- CPT 90750 Zoster (shingles) vaccine, recombinant, sub-unit, adjuvanted, for intramuscular use;
- NDC 58160081912 SHINGRIX 50 MCG/0.5 KIT;
- NDC 58160082311 SHINGRIX 50 MCG/0.5 KIT;
- NDC 58160082801 SHINGRIX GE ANTIGEN COMPONENT 50 MCG VIAL;
- NDC 58160082803 SHINGRIX GE ANTIGEN COMPONENT 50 MCG VIAL;
- NDC 58160082901 SHINGRIX ADJUVANT COMPONENT VIAL;
- NDC 58160082903 SHINGRIX ADJUVANT COMPONENT VIAL.

[1] *CPT copyright 2022 American Medical Association.*

All rights reserved. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

CPT is a registered trademark of the American Medical Association.

RZV is a 2 dose vaccine; it is recommended that the second RZV dose be given 2 – 6 months after the first, or 1 – 2 months after the first if needed among people with weakened immune systems.[9] Patients will be classified into exposure cohorts based on their exposure to the first or second dose of RZV. Since the procedure codes and NDCs used to identify RZV do not distinguish between doses, first and second doses will be identified based on the number of RZV administrations observed. The first dose will be defined as the first RZV administration during the study period with no RZV administrations in the prior 365 days, while second RZV doses will be those administrations that occur 1-6 months after the first dose. To account for delays in the vaccination schedule, a 30-day one-sided grace period will be applied such that RZV second doses will be identified up to 7 months after the first dose.

9.3.5. Identification of Outcomes

9.3.5.1. Primary Outcome (Effectiveness)

The primary outcome for this study is the occurrence of new HZ infection. Occurrence of new HZ infection will be identified by the first presence of a diagnosis code for HZ infection (ICD-10 code: B02, Zoster [herpes zoster]) on at least one claim during follow-up. This algorithm was based on previous studies by Yawn et al.[16] and Kim et al.[17] which found that the positive predictive values (PPVs) for the presence of one diagnosis code for HZ were 85.2% and 86.2%, respectively, compared to the gold standard of medical record review.

Due to the administrative claims process, patients may receive a diagnosis code for HZ infection on the date of RZV receipt. For this reason, diagnostic codes for HZ infection that occur on the date of receipt of RZV will not be used to exclude prevalent cases of HZ (Section 9.2.2) and will not be counted as outcomes (Section 9.2.5).

9.3.5.2. Secondary Outcome (Safety)

The secondary outcome for this study is disease flare: UC flare within the UC cohorts and RA flare within the RA cohorts.

For the UC cohorts, the secondary outcome will be defined by an algorithm based on the claims-based indicator of UC flare in the 90 days following the cohort entry date. Based on published literature,[18,19] the claims-based composite algorithm of UC flare will include a combination of the following components:

- Change in UC therapy (ie, new start or switch);
    - Corticosteroids (oral, rectal, or injection);
    - 5-aminosalicylates (oral or rectal);
    - Immunosuppressants (ie, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus);
- Emergency room visit with UC as primary diagnosis;

- Hospitalization with UC as primary diagnosis;
- UC-related surgery (ie, colectomy, proctocolectomy).

For the RA cohorts, the secondary outcome will be defined by an algorithm based on the occurrence of a claims-based indicator of RA flare in the 90 days following cohort entry date. Based on published literature,[20,21,22,23] claims-based composite algorithm of RA flare will include a combination of the following components:

- Change in RA therapy (eg, new start or switch from monotherapy to combination therapy);
    - Corticosteroids (oral or injection): initiation of, or change in, treatment with a short-acting oral glucocorticoid (eg, methylprednisolone 6-day dosing pack) or any parenteral glucocorticoid injection, excluding corticosteroids administered the same day as infusions for RA therapy;
    - Conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) (ie, methotrexate, sulfasalazine, hydroxychloroquine, leflunomide);
- Emergency room visit with RA as primary diagnosis;
- Hospitalization with RA as primary diagnosis.

The claims-based indicators of disease flare will be identified based on drug (NDC and American Hospital Formulary Service [AHFS]), procedure (Healthcare Common Procedure Coding System [HCPCS], CPT®[2], and International Classification of Diseases, 10th Revision, Procedure Coding System [ICD-10-PCS]), and diagnosis (ICD-10) codes. The specific codes that will be utilized to identify UC and RA disease flares are provided in Annex 3.

For both UC and RA flare, a new start or switch will be defined as a dispensing of one of the medications listed above with no dispensing for the same medication in the prior 365 days. As long-term corticosteroids are widely used in the treatment of RA,[24] this definition will help distinguish between a new dispensing for the treatment of flare versus long-term therapy. Additionally, days' supply of oral corticosteroids will be taken into account to identify short-acting treatments (eg, limiting to dispensing with a days' supply of 7 days or less).

9.3.6. Covariates

Members of the study cohorts will be described according to claims-based covariates. Unless otherwise specified, diagnoses will be identified through the presence of ICD-10 codes, while prescription medications will be identified through pharmacy dispensings or administrations. No over-the-counter medications will be assessed. Drug use and disease status will be

[2] CPT copyright 2022 American Medical Association. All rights reserved.

categorized as yes (code present) or no (no code present). Demographic attributes will be determined on the cohort entry date while other factors will be assessed during the 365-day baseline period, unless otherwise specified. In addition to the covariates listed below, the 50 most common diagnoses, procedures, and medications will be described during the baseline period.

9.3.6.1. Demographic Characteristics

- Age;
- Sex;
- Race/Ethnicity;
- Geographic location;
- Data source (ORD or MA-PD).

9.3.6.2. Healthcare Utilization

- Number of outpatient visits;
- Number of emergency department visits;
- Number of 3-digit diagnosis codes;
- Number of drugs dispensed;
- Hospitalizations;
    - Number of hospitalizations;
    - Number of inpatient days (among patients who have been hospitalized).

9.3.6.3. Comorbid Conditions

- Human immunodeficiency virus (HIV) infection;
- Malignancy, excluding non-melanoma skin cancer;
- Diabetes mellitus (type 1 and type 2);
- Other autoimmune diseases (eg, psoriatic arthritis, ankylosing spondylitis, systemic lupus erythematosus, Crohn's disease, Graves' disease, multiple sclerosis);
- Cardiovascular disease;
- Serious infections

9.3.6.4. Treatment History

- Tofacitinib treatment;
  - Tofacitinib dose;
    - Average daily dose in prior 91 days;
    - Cumulative dose in prior 365 days;
  - Treatment duration;
- Zostavax® vaccination;
- TNF inhibitor treatment (eg, etanercept, adalimumab, golimumab, infliximab, certolizumab);
- Non-TNF biologics (eg, abatacept, rituximab, tocilizumab, sarilumab, anakinra, ustekinumab, vedolizumab);
- csDMARD treatment (eg, methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, azathioprine);
- Immunosuppressants (eg, azathioprine, 6-mercaptopurine, cyclosporine);
- JAK inhibitor treatment (eg, baricitinib, upadacitinib);
- Corticosteroid treatment;
  - Average daily dose (eg, None, ≤5 mg/day, >5 to ≤10 mg/day, >10 to ≤20 mg/day, and >20 mg/day of prednisone average dose equivalent);
    - During 30 days prior to cohort entry;
    - During 365 days prior to cohort entry;
- Number of treatments for UC/RA prior to cohort entry;
- Chemotherapy;
- Radiotherapy;
- 5-aminosalicylates (eg, mesalamine, balsalazide, olsalazine);
- Ozanimod.

Additional therapies that are approved for the treatment of UC or RA may be incorporated if they become available. All of the above covariates may be considered for inclusion in the propensity score model used for IPTW.

9.3.6.5. Current Treatment

Medications assessed between the cohort entry date and end of follow-up (as defined in Section 9.2.5) will be included in descriptive analyses only and will not be included in the propensity score models. The medications include:

- Tofacitinib treatment;
    - Dose;
    - Treatment duration;
- TNF inhibitor treatment (eg, etanercept, adalimumab, golimumab, infliximab, certolizumab);
- Non-TNF biologics (eg, abatacept, rituximab, tocilizumab, sarilumab, anakinra, ustekinumab, vedolizumab);
- csDMARD treatment (eg, methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, azathioprine);
- Immunosuppressants (eg, azathioprine, 6-mercaptopurine, cyclosporine);
- Other JAK inhibitor treatment (eg, baricitinib, upadacitinib);
- Corticosteroid treatment;
    - Average daily dose (eg, None, ≤5 mg/day, >5 to ≤10 mg/day, >10 to ≤20 mg/day, and >20 mg/day of prednisone average dose equivalent;
- 5-aminosalicylates (eg, mesalamine, balsalazide, olsalazine);
- Ozanimod.

Additional therapies that are approved for the treatment of UC or RA may be incorporated if they become available.

9.4. Data Sources

The patients included in this study will be drawn from the ORD and the Optum MA-PD, each as described below. The use of 2 databases is necessary to enable the findings from this study to be generalized to adults aged 18 years and older. The ORD will provide data on

adults under 65 years of age and MA-PD will provide data on adults 65 years of age and older (the ORD also includes some adults age 65+ years). The same patient does not appear in the 2 data sources simultaneously and the MA-PD operates similarly to the ORD, allowing us to easily pool the data for analysis.

As indicated in Section 9.2.3.2, RZV exposed patients will be matched to RZV unexposed patients from the same data source.

9.4.1. Optum Research Database

The ORD is a proprietary research database that contains the eligibility data, medical claims, and pharmacy claims from a large, commercial health plan affiliated with Optum. The individuals covered by this health plan are geographically diverse across the United States and comprise approximately 3% to 4% of the US population. As early as 1993, medical and pharmacy claims data are available for 65 million individuals with both medical and pharmacy benefit coverage. For 2021, data are available for approximately 12.6 million individuals with medical and pharmacy coverage.

Optum research activities utilize de-identified data from the ORD. Patient-identifiable information can only be accessed following approval of the study protocol by an appropriate institutional review board and privacy board. All data access conforms to applicable Health Insurance Portability and Accountability Act policies.

Accessible information from the ORD includes demographics, pharmacy use, and all medical and facility claims, which provide data on services, procedures, and their accompanying diagnoses.

The coding of medical claims conforms to insurance industry standards including:

- Use of designated claims forms (eg, physicians use the Health Care Financing Agency-1500 format and hospitals use the UB-04 or UB-92 format);
- International Classification of Diseases, 9th Revision codes;
- ICD-10 codes;
- CPT® codes[3];
- HCPCS codes;
- Cost information;
- De-identified patient and provider codes.

[3] CPT copyright 2022 American Medical Association. All rights reserved.

Claims for pharmacy services are typically submitted electronically by the pharmacy at the time prescriptions are filled. Pharmacy claims data allowing for longitudinal tracking of medication refill patterns and changes in medications include:

- NDC;
- Drug name;
- Dosage form;
- Drug strength;
- Fill date;
- Days of supply;
- Cost information;
- De-identified patient and prescriber codes.

An important advantage of the ORD is the large number of patients that can be studied because the data are routinely collected and maintained in computerized data files. The completeness of the data allows investigators to link any number of patient, physician, and treatment attributes, while maintaining the de-identified nature of the data. The database also captures a longitudinal record of medical services, irrespective of treatment site.

9.4.2. Optum Medicare Advantage and Medicare Part D Data

Beginning in 2006, complete medical and pharmacy information is available for Medicare enrollees with medical and Medicare Part D coverage. The pharmacy claims contain sufficient information to trace patients' pharmacy expenditures through the multiple phases of the Medicare Part D plans. For 2021, data are available for approximately 7.0 million individuals with both medical and pharmacy benefit coverage. Underlying information is geographically diverse across the country and fairly representative of the US Medicare population. Optum research activities utilize de-identified data from MA-PD. In limited instances, patient identifiers may be accessed where applicable law allows the use of patient-identifiable data, and when the study obtains appropriate approvals for accessing data that are not de-identified.

9.4.3. Supplemental Data Sources

9.4.3.1. Sociodemographic Data

Optum has a unique source of individual-level data, which is linked to the administrative claims data that allows for analysis of socioeconomic characteristics. The data populating these socioeconomic elements are generated by a combination of self-report, modeling, census data, classification based on surname and/or geography, and a variety of other

individual-level and population-level data sources. From this source of sociodemographic data, Optum will include race/ethnicity as a covariate for this study.

9.5. Study Size

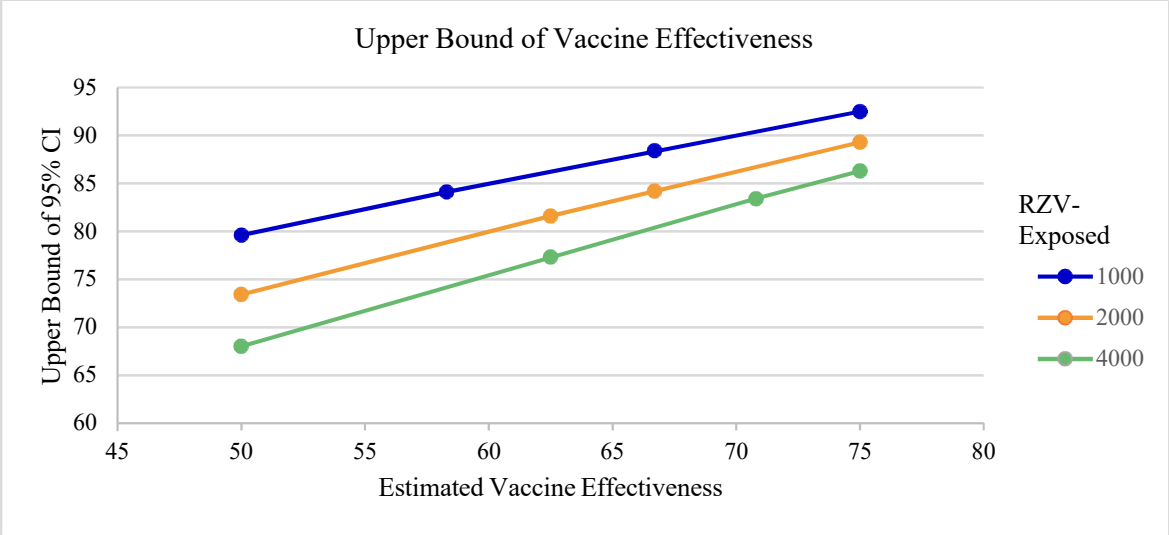
Table 1 displays the counts of patients with RA and UC, and with RZV and tofacitinib exposure, that were observed in the ORD and MA-PD between October 2017 and December 2022. This count is for informational purposes only. Final sample size for the study could change depending upon criteria applied during the conduct of the protocol and required approvals.

Table 1. Counts of Tofacitinib and RZV Recipients Among Adults (18+) with RA or UC: ORD and MA-PD October 2017 to December 2022

Patient Characteristics	N
Patients with RA	446,618
Patients with UC	202,619
Patients with RA and/or UC	639,868
With a dispensing of tofacitinib	12,491
With receipt of RZV	100,005
With a dispensing of tofacitinib and receipt of at least one dose of RZV	2,744
With a dispensing of tofacitinib and receipt of two doses of RZV	1,932

Of the 2,744 tofacitinib users with RA or UC who received at least one dose of RZV, there were 1,932 (70%) who received two doses of RZV. These patients had a median of 11 tofacinib dispensings, suggesting that there may be a subset of patients with tofacitinib exposure that overlaps both RZV doses. Assuming a background rate of HZ of 1.2 cases per 100 person-years among non-tofacitinib exposed patients with UC and RA[25] and an effectiveness of RZV in preventing HZ of 85%[26] among non-tofacitinib exposed patients with RA or UC, the sample size necessary to exclude 85% from the 95% confidence interval for the RZV effectiveness estimate for tofacitinib exposed patients with RA or UC was calculated. Figure 6 displays the upper bound of the 95% confidence interval for a range of estimated vaccine effectiveness and population sizes. Thus, for 2,000 RZV-exposed person-years, the upper 95% confidence interval bound of vaccine effectiveness would exclude 85% if the point estimate among tofacitinib exposed patients with RA or UC were 66.7% or lower (corresponding to an effect size of 21.5%, meaning that tofacitinib reduces the RZV effectiveness by 21.5%). For 4,000 RZV-exposed person-years, the estimated 95% confidence interval would exclude 85% if the point estimate among tofacitinib exposed patients with RA or UC were 70.8% or lower (corresponding to an effect size of 16.7%, meaning that tofacitinib reduces the RZV effectiveness by 16.7%). These estimates are generated for a range of plausible population sizes based on Optum feasibility counts shown in Table 1.

Figure 6. Upper Bound of Vaccine Effectiveness for a Range of Population Sizes and Vaccine Effectiveness Estimates



Assumptions: 1.2% HZ rate in unexposed; 2:1 matching of comparators to RZV exposed patients[27]

Table 2. Prevalence of Zostavax Vaccination and Duration of Enrollment Among Adults (18+) with RA or UC Treated with Tofacitinib and Shingrix: Optum Claims Database, October 2017 to July 2022

	Patients with Tofacitinib and Shingrix	
	Patients <60 years of age N (%)	Patients ≥60 years of age N (%)
Total patients	649 (100.0%)	1,248 (100.0%)
Patients with a claim for Zostavax[a]	16 (2.5%)	94 (7.5%)
With at least 1 year of enrollment prior to Shingrix[a]	544 (83.8%)	1,069 (85.7%)
Patients with a claim for Zostavax[b]	16 (2.9%)	87 (8.1%)
With at least 2 years of enrollment prior to Shingrix[a]	437 (67.3%)	859 (68.8%)
Patients with a claim for Zostavax[b]	15 (3.4%)	83 (9.7%)
With at least 3 years of enrollment prior to Shingrix[a]	340 (52.4%)	667 (53.5%)
Patients with a claim for Zostavax[b]	13 (3.8%)	74 (11.1%)
With at least 4 years of enrollment prior to Shingrix[a]	264 (40.7%)	519 (41.6%)
Patients with a claim for Zostavax[b]	10 (3.8%)	68 (13.1%)
With at least 5 years of enrollment prior to Shingrix[a]	205 (31.6%)	388 (31.1%)
Patients with a claim for Zostavax[b]	7 (3.4%)	52 (13.4%)

[a] Denominator for percent is the number of patients in the relevant age category (<60, ≥60).
[b] Denominator for percent is the number of patients with the duration of enrollment (eg, 1, 2, etc) in the row above.

The prevalence of prior Zostavax vaccination and duration of enrollment among UC and RA patients treated with tofacitinib and Shingrix is shown in Table 2. Among patients under age 60 years, 2.5% had prior exposure to Zostavax whereas 7.5% of patients 60 years of age and older had Zostavax exposure. Regarding duration of enrollment prior to receipt of Shingrix, over 80% of patients in both age groups had at least 1 year, while slightly more than 30% had at least 5 years of enrollment.

9.6. Data Management

All data management and analysis will be conducted using Statistical Analysis System (SAS) version 9.4 (SAS Institute Inc., Cary, NC) and SAS Enterprise Guide 6.1 or later. The data will be extracted from the ORD once. The report will include the structured ORD and MA-PD data only.

9.7. Data Analysis

9.7.1. Propensity Score Modeling

Propensity scores that discriminate between receipt and non-receipt of RZV will be created from a wide variety of baseline demographic, comorbidity, disease severity (based on proxies for disease severity, such as treatment with advanced therapy), and comedication indicators. The propensity scores will be used to calculate IPTW to adjust for potential confounding in the comparative analysis.

There will be 4 propensity score models that, separately, will estimate propensity scores that discriminate between (1) receipt of two doses of RZV and non-receipt of RZV in UC cohorts, (2) receipt of two doses of RZV and non-receipt of RZV in RA cohorts, (3) receipt of at least one dose of RZV and non-receipt of RZV in UC cohorts, and (4) receipt of at least one dose of RZV and non-receipt of RZV in RA cohorts. If there are confounders identified that would only be appropriate to include in one model and not the other, separate propensity score models for the outcomes HZ and disease flare will be considered.

Propensity score modeling will be performed to determine and analyze the predictors of RZV receipt, incorporating dozens of predictors of vaccination status (such as age, sex, comorbidities, and concomitant medications). Propensity scores will be estimated using logistic regression that includes predictors of vaccination, including pre-specified covariates (ie, covariates included in Section 9.3.6.1 – 9.3.6.4) and empirically identified covariates based on the most frequently occurring diagnoses, procedures, and medications dispensed, as independent variables in the model and receipt of 2 doses of RZV/non-receipt (or receipt of at least 1 dose of RZV/non-receipt) as the dependent variable. Only covariates assessed during the 365-day baseline period and known (or highly suspected) to be confounders will be included in the propensity score model. The list of empirically identified covariates will be reviewed, and those covariates that are known risk factors of HZ or UC/RA disease flares will be identified and considered for inclusion in the propensity score model. Those covariates that are correlates of RZV receipt but are not risk factors for the outcomes (and therefore not confounders) will be removed from consideration. Some pre-specified

covariates may be closely correlated with the empirically identified variables. For variable pairs that are highly correlated (eg, correlation >0.9), one will be eliminated (retaining pre-specified covariates where possible). In addition, age, sex, and the interaction between age and sex will be included in the model to ensure adequate control of confounding by these variables. Additional details on model selection will be described in the SAP.

For a patient with a given covariate pattern, the propensity score will be the fitted value of the probability of that patient being a member of the RZV 2-Dose or RZV ≥1 Dose cohorts, given membership in the study population and the covariate pattern. To the extent that the decision to receive RZV for a particular patient depends on the health characteristics of the patient at the time of the decision, the propensity score models the clinical decision-making process. Additional details on the propensity score models will be described in the SAP.

Once the final models have been generated, propensity scores will be estimated for each patient.

Optum has extensive experience with propensity scores and has been involved in methodological development, application and explanations of the propensity score.[28,29,30,31]

9.7.2. Inverse Probability of Treatment Weighting

The propensity scores will be used to calculate IPTW and weight each patient in the exposure cohorts. This will be performed separately for the RZV 2-Dose and RZV ≥1 Dose analyses. IPTW produces weighted groups that have similar patterns of the presence or absence of a large number of factors. With IPTW, the balance between the comparison cohorts can be expected to be similar to or better than would be achieved in a randomized trial with respect to all identified covariates. Matching on the propensity score will be considered as an alternative approach, but IPTW has the advantage that fewer eligible patients would be excluded due to their inability to match.

The IPTW will be defined such that the causal estimate is the average treatment effect in the treated (ATT).[32] Two sets of IPTW will be estimated, one for the UC cohorts and one for the RA cohort. Briefly, to estimate the ATT, the weights are defined such that every RZV-exposed patient receives a weight of one, while the unexposed patients receive weights that are a function of the propensity score:

$$w_{ATT} = Z + \frac{e(1-Z)}{1-e},$$

where Z is the indicator for RZV exposure and e is the propensity score,

$$e = \Pr(Z = 1|X).$$

The propensity score is the probability of receiving RZV as a function of **X**, a vector of the predictors of RZV exposure.

Balance of covariates among the IPT weighted cohorts will be assessed using the standardized difference (SD) comparing the weighted study cohorts. Any variables with an absolute SD >0.1 may be considered imbalanced. If specific variables remain imbalanced after weighting, they will be included as independent predictors in outcome models. Overall balance between the cohorts, both before and after weighting, will be assessed via overlap (or lack thereof) in histograms of the weights. Trimming of extreme weights will be considered.[33]

9.7.3. Descriptive Analysis and Estimation of Risk

The report will include a flow chart depicting the number of patients that meet all study eligibility criteria. The study cohorts before and after IPTW will be described according to the baseline characteristics listed in Section 9.3.6.

9.7.3.1. RZV 2-Dose Analysis

The RZV 2-dose analysis will be used as the main analysis for assessment of the primary objective for effectiveness. Incidence rates and corresponding 95% confidence intervals for the primary outcome (HZ) will be calculated before and after weighting. All analyses will be performed separately within the UC and RA cohorts. The incidence rate of HZ in the RZV 2-Dose cohort will be compared to the Comparator 2-Dose cohort. Weighted Kaplan-Meier plots will be used to depict the cumulative probability of survival (non-occurrence of the event).

Given the sampling approach that will be utilized in this study (sampling with replacement), we will calculate the number of patients that were selected and included in a study cohort more than once (Section 9.2.3.2.1). If that number exceeds 10% of the study population, then covariance between observations will be taken into account using an appropriate method (eg, generalised estimating equations or robust variance estimators).

The relative hazard will be calculated through weighted Cox regression models with appropriate 95% confidence intervals. Known confounders that are strongly associated with RZV receipt and HZ may also be included in the regression models as well as any variables with an absolute SD >0.1 between weighted exposure cohorts. Additional details on model selection will be detailed in the SAP.

Patients will be further stratified by the following patient groups relative to their matched comparators:

1. Tofacitinib current users at time of receipt of first and second RZV doses;

2. Tofacitinib current users at time of receipt of second RZV dose only.

The first subgroup analysis conducted among patients who receive two doses of RZV and are current users of tofacitinib at the time of receipt of both doses will be the main comparison.

9.7.3.2. RZV ≥1 Dose Analysis

The RZV ≥1 dose analysis will be used to assess the secondary objectives for effectiveness and safety. Incidence rates and corresponding 95% confidence intervals for the primary (HZ) and secondary (disease flare) outcomes will be calculated before and after weighting in each of the 4 RZV ≥1 Dose and Comparator ≥1 Dose cohorts. All analyses will be performed separately within the UC and RA cohorts. The incidence rate of each outcome in the RZV ≥1 Dose cohort will be compared to the Comparator ≥1 Dose cohort. Weighted Kaplan-Meier plots will be used to depict the cumulative probability of survival (non-occurrence of the event).

As in the RZV 2-dose analysis (Section 9.7.3.1), we will calculate the number of patients that were selected and included in a study cohort more than once. If that number exceeds 10% of the study population, then covariance between observations will be taken into account using an appropriate method (eg, generalised estimating equations or robust variance estimators).

The relative hazard will be calculated through weighted Cox regression models with appropriate 95% confidence intervals. Known confounders that are strongly associated with receipt of at least one RZV dose and the study outcomes may also be included in the regression models as well as any variables with an absolute SD >0.1 between weighted exposure cohorts. Additional details on model selection will be detailed in the SAP

9.7.4. Sensitivity Analysis

For sensitivity analyses, Optum will investigate alternative eligibility requirements of tofacitinib exposure, including the creation of a separate set of RZV 2-Dose, RZV ≥1 Dose, and matched comparator cohorts that include current tofacitinib users and recent tofacitinib users within given time intervals, such as 8 weeks, preceding cohort entry. The inclusion of recent tofacitinib users will maximize sample size while allowing for observation of study outcomes among patients with tofacitinib treatment spanning both RZV doses as well as those patients with tofacitinib treatment overlapping with only one of the RZV doses. This approach will allow for the evaluation of effectiveness and safety across a range of real-world use patterns and address the potential for extended immunosuppressant effects of tofacitinib following discontinuation. Recent tofacitinib users will be identified as patients who met the current user definition within the past 8 weeks (or other specified time interval). A tofacitinib recent-treatment period will be defined as starting on the day following the end of the on-treatment period (ie, end of tofacitinib days' supply plus a 30-day grace period) and continue for a duration of 8 weeks. Depending on sample size, periods of recent use shorter or longer than 8 weeks may be considered. In this sensitivity analysis, patients who receive a second dose of RZV with the second dose occurring during a tofacitinib on-treatment period or 8-week recent-treatment period on or after the study initiation date will be included in the RZV 2-Dose cohort. Similarly, patients who receive a first administration of RZV during a tofacitinib on-treatment period or a tofacitinib 8-week recent-treatment period on or after the study initiation date, with no administration of RZV in the prior 365 days, will be included in the RZV ≥1 Dose cohort. Each of the RZV cohorts will be time-matched to comparators who also meet the definition of current or recent user of tofacitinib. This analysis will

include the 2-dose and ≥1 dose analyses for primary and secondary outcomes.

In addition, using the main study cohorts, Optum will consider applying a more restrictive definition of current tofacitinib exposure (ie, not including the 30-day grace period when identifying current tofacitinib users), and according to cumulative tofacitinib dose. To assess a potential dose-response relationship between tofacitinib exposure and study outcomes, a sensitivity analysis will be performed in which the cohorts are stratified based on tofacitinib dose. Specifically, the daily dose of tofacitinib will be calculated based on dispensings received in the 91 days prior to cohort entry and then the cohorts will be stratified according to high versus low dose of tofacitinib based on the median daily dose. In addition, the cohorts will also be stratified based on cumulative dose of tofacitinib received in the 365 days prior to cohort entry. As patient follow-up will not be censored upon discontinuation of tofacitinib treatment, a sensitivity analysis will be conducted in which patients are stratified based on continued exposure to tofacitinib during follow-up.

As the study period includes time before and during the COVID-19 pandemic, a sensitivity analysis will be conducted stratified by calendar time (cohort entry prior to 20 January 2020 and cohort entry on or after 20 January 2020).

A quantitative bias analysis will also be performed to assess the potential magnitude of bias due to unmeasured confounding, including confounding by incompletely captured or missing covariates (eg, UC/RA severity). A standard epidemiological spreadsheet will be used to assess the robustness of the results in the presence of an unmeasured confounder.[34] The results of the main analyses for the association between RZV exposure and the primary and secondary outcomes along with varying magnitudes of the confounder-outcome association and confounder-RZV association will be used to calculate the difference from the observed findings after accounting for the unmeasured confounder. The range of associations to be applied for the confounder-outcome and confounder-RZV associations will be informed by published literature and associations observed for related variables in the current study.

As patients that have UC and RA may have different clinical characteristics compared to patients that have only one of the two diseases, the number of patients that have both diagnoses will be quantified. Additionally, a sensitivity analysis will be conducted in which the association between RZV exposure and the primary and secondary outcomes is assessed after excluding patients with both UC and RA from the exposure cohorts.

To assess the effect of prior Zostavax vaccination on subsequent RZV effect, an analysis will be performed where the study population is restricted to patients with at least 5 years of enrollment prior to cohort entry. Within this subset, the analysis will be conducted separately among patients with and without Zostavax vaccination during this baseline 5-year period. The effect of prior Zostavax exposure will be informed by the extent to which the estimate of RZV effect differs according to strata of prior Zostavax exposure.

It is possible that the comparator cohorts could include patients previously vaccinated with RZV more than 365 days earlier. To address this potential exposure misclassification, a sensitivity analysis will be performed, for which the study population will be restricted to patients with enrollment that extends back to 20 October 2017 and who do not have any prior administration of RZV during that time. Finally, a sensitivity analysis will be conducted for HZ in which patients are stratified based on their amount of available follow-up time.

Misclassification of disease flares is possible when using claims-based algorithms (for example, patients may change therapy for reasons other than disease flares), leading to over- or under-estimation of the outcome; thus, alternative definitions will be explored and outlined in the SAP as sensitivity analyses. Specifically, sensitivity analysis will explore using a more conservative definition based on only UC-related surgeries or ER and hospitalizations with UC or RA as the primary diagnosis, as well as evaluating more expansive definitions inclusive of other medications of interest, such as biologics or other JAK inhibitor treatments.

Additional sensitivity analysis may be performed if needed.

9.8. Quality Control

The ORD contains data derived from claims submitted by providers and pharmacies to obtain payment for health care services rendered, data to track plan membership for premium billing, and provider data to track participating physicians who have contracts with health plans to provide services. The underlying administrative data are routinely captured, verified, automated, and de-identified. The data undergo regular audits and quality control procedures by the insurer and are updated monthly. Although the health insurance claims data represent financial transactions and are not research records, the financial transactions related to the services provided create financial incentives to record them correctly and fully, so the billable medical services represented in the database are likely to be complete. The validity of this claims research database for epidemiologic research (as compared with data abstracted from medical records) has been widely published.[35,36,37,38]

The study will be carried out according to the Optum Epidemiology group's internal SOPs that are consistent with the International Society for Pharmacoepidemiology's (ISPE) Guidelines for Good Pharmacoepidemiology Practices.[39] In particular, the SOPs in place at Optum prescribe that processes and deliverables are documented, reviewed, and validated in sufficient detail to allow for subsequent re-examination or replication.

The validation of analytic work typically involves a combination of a review of program logs and lists, independent coding, a review of program processes and documentation to ensure departmental SOPs are followed, and reconciliation of program code to ensure populations and results are consistent with what is needed for the particular study. Individual programs are documented and revised as needed until sign-off by a validation analyst using a validation/programming log.

9.9. Limitations of the Research Methods

This study is based on an analysis of automated medical and prescription claims. While claims data are extremely valuable for the efficient and effective examination of health care outcomes, treatment patterns, health care resource utilization and costs, all claim databases have certain inherent limitations because the claims are collected for the purpose of payment, not research. The presence of a claim for a filled prescription does not indicate that the medication was consumed or that it was taken as prescribed. Medications filled over the counter or provided as samples by the physician will not be observed in the claims data. The presence of a diagnosis code on a medical claim is not confirmation of disease, as the diagnosis code may be incorrectly coded or included as rule-out criteria rather than actual disease. Duration of follow-up can be limited in the claims data due to individuals changing health insurance plans.

Clinical variables are missing for some individuals as a result of variation in care practices and potentially other factors. When these data are missing in systematic ways, care must be taken in selecting the study population and, often, analytic methods to account for the missing data are needed. Claims data include limited information on socioeconomic characteristics. For this study, Optum will include race/ethnicity captured in a data source which is linked to the administrative claims data. However, data on race/ethnicity may be missing for some individuals.

Since identification of the second dose of RZV is dependent on the observation of the first dose of RZV, it is possible that a second RZV dose may be misclassified as a first RZV dose if the first dose is not captured in the claims data. However, given the recommended spacing of 1-6 months between doses and the required 12 months of continuous enrollment prior to cohort entry, this misclassification is expected to be infrequent.

In addition, as the definition of UC or RA disease flares proposed by this study is based on a composite algorithm inclusive of diagnosis codes and treatment patterns, outcome misclassification is possible, and results should be interpreted in light of this limitation. For example, a patient may change medications for reasons other than disease flares. However, a similar claims-based algorithm inclusive of treatment patterns to identify disease flares following RZV administration has been used in literature.[23]

Because accrual of eligible cohort members depends on actual use of RZV and tofacitinib within the insured population that is the source for the study, divergence in numbers of users from sample size projections might affect how rapidly the study power reaches an adequate level.

9.10. Other Aspects

Not applicable.

10. PROTECTION OF HUMAN SUBJECTS

10.1. Patient Information

This study involves data that exist in anonymised structured format and contain no patient personal information.

10.2. Patient Consent

As this study involves anonymised structured data, which according to applicable legal requirements do not contain data subject to privacy laws, obtaining informed consent from patients by Pfizer is not required.

10.3. Institutional Review Board (IRB)/Independent Ethics Committee (IEC)

There must be prospective approval of the study protocol, protocol amendments, and other relevant documents (eg, informed consent forms if applicable) from the relevant IRBs/IECs. All correspondence with the IRB/IEC must be retained. Copies of IRB/IEC approvals must be forwarded to Pfizer.

10.4. Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and follow generally accepted research practices described in Guidelines for Good Pharmacoepidemiology Practices issued by the ISPE, and the European Medicines Agency, European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology.

11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study involves data that exist as structured data by the time of study start. In these data sources, individual patient data are not retrieved or validated, and it is not possible to link (ie, identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an adverse event (AE) (ie, identifiable patient, identifiable reporter, a suspect product, and event) cannot be met.

12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

In the event of any prohibition or restriction imposed (eg, clinical hold) by an applicable competent authority in any area of the world, or if the investigator is aware of any new information which might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately.

13. REFERENCES

1. Ford AC, Moayyedi P, Hanauer SB. Ulcerative colitis. BMJ. Feb 5 2013;346:f432. doi:10.1136/bmj.f432.

2. Alamanos Y, Drosos AA. Epidemiology of adult rheumatoid arthritis. Autoimmun Rev. Mar 2005;4(3):130-6. doi:10.1016/j.autrev.2004.09.002.

3. Doran MF, Crowson CS, Pond GR, O'Fallon WM, Gabriel SE. Frequency of infection in patients with rheumatoid arthritis compared with controls: a population-based study. Arthritis Rheum. Sep 2002;46(9):2287-93. doi:10.1002/art.10524.

4. Long MD, Martin C, Sandler RS, Kappelman MD. Increased risk of herpes zoster among 108 604 patients with inflammatory bowel disease. Aliment Pharmacol Ther. Feb 2013;37(4):420-9. doi:10.1111/apt.12182.

5. Winthrop KL, Yamanaka H, Valdez H, et al. Herpes zoster and tofacitinib therapy in patients with rheumatoid arthritis. Arthritis Rheumatol. Oct 2014;66(10):2675-84. doi:10.1002/art.38745.

6. Winthrop KL, Melmed GY, Vermeire S, Long MD, Chan G, Pedersen RD, Lawendy N, Thorpe AJ, Nduaka CI, Su C. Herpes Zoster Infection in Patients With Ulcerative Colitis Receiving Tofacitinib. Inflamm Bowel Dis. 2018 Sep 15;24(10):2258-2265. doi: 10.1093/ibd/izy131. PMID: 29850873; PMCID: PMC6140434.

7. Xeljanz® [package insert]. New York, NY: Pfzier, Inc.; December 2021.

8. Anderson TC, Masters NB, Guo A, Shepersky L, Leidner AJ, Lee GM, Kotton CN, Dooling KL. Use of recombinant zoster vaccine in immunocompromised adults aged ≥ 19 years: recommendations of the advisory committee on immunization practices—United States, 2022. MMWR. Jan 2022;71(3):80-84.

9. Food and Drug Administration. Shingrix [package insert], revised: 07/2021. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2021. https://www.fda.gov/media/108597/download

10. Satyam VR, Li PH, Reich J, Qazi T, Noronha A, Wasan SK, Farraye FA. Safety of Recombinant Zoster Vaccine in Patients with Inflammatory Bowel Disease. Dig Dis Sci. 2020 Oct;65(10):2986-2991. doi: 10.1007/s10620-019-06016-4. Epub 2020 Jan 2. PMID: 31897892.

11. Stevens E, Weinblatt ME, Massarotti E, Griffin F, Emani S, Desai S. Safety of the Zoster Vaccine Recombinant Adjuvanted in Rheumatoid Arthritis and Other Systemic Rheumatic Disease Patients: A Single Center's Experience With 400 Patients. ACR Open Rheumatol. 2020 Jun;2(6):357-361. doi: 10.1002/acr2.11150. Epub 2020 May 15. PMID: 32412669; PMCID: PMC7301873.

12. Food and Drug Administration. Real-world data: assessing electronic health records and medical claims data to support regulatory decision-making for drug and biological products. Guidance for industry. September 2021. Accessed April 18, 2022. https://www.fda.gov/media/152503/download.

13. Food and Drug Administration. Considerations for the use of real-world data and real-world evidence to support regulatory decision-making for drug and biological products. Guidance for industry. December 2021. Accessed April 18, 2022. https://www.fda.gov/media/154714/download.

14. Suissa S. Effectiveness of inhaled corticosteroids in chronic obstructive pulmonary disease: immortal time bias in observational studies. Am J Respir Crit Care Med. 2003;168(1):49-53.

15. Sun Y, Kim E, Kong CL, Arnold BF, Porco TC, Acharya NR. Effectiveness of the Recombinant Zoster Vaccine in Adults Aged 50 and Older in the United States: A Claims-Based Cohort Study. Clin Infect Dis. 2021 Sep 15;73(6):949-956. doi: 10.1093/cid/ciab121. PMID: 33580245; PMCID: PMC8442779.

16. Yawn BP, Wollan P, St Sauver J. Comparing shingles incidence and complication rates from medical record review and administrative database estimates: how close are they? Am J Epidemiol. 2011 Nov 1;174(9):1054-61. doi: 10.1093/aje/kwr206.

17. Kim YS, Seo HM, Bang CH, Lee JH, Park YG, Kim YJ, Kim GM, Park CJ, Park HJ, Yu DS, Lee JY, Park YM. Validation of Herpes Zoster Diagnosis Code in the Electronic Medical Record: A Retrospective, Multicenter Study. Ann Dermatol. 2018 Apr;30(2):253-255. doi: 10.5021/ad.2018.30.2.253.

18. Lund JL, Stürmer T, Porter CQ, Sandler RS, Kappelman MD. Thiazolidinedione use and ulcerative colitis-related flares: an exploratory analysis of administrative data. Inflamm Bowel Dis. 2011;17(3):787-794. doi:10.1002/ibd.21348

19. Burisch J, Zhang H, Choong CK, Nelson D, Naegeli A, Gibble T, Goetz I, Egeberg A. Validation of claims-based indicators used to identify flare-ups in inflammatory bowel disease. Therap Adv Gastroenterol. 2021 Mar 31;14:17562848211004841. doi: 10.1177/17562848211004841. PMID: 33868458; PMCID: PMC8020737.

20. Lodi S, Evans SJ, Egger P, Carpenter J. Is there an anti-inflammatory effect of statins in rheumatoid arthritis? Analysis of a large routinely collected claims database. Br J Clin Pharmacol. 2010;69(1):85-94. doi:10.1111/j.1365-2125.2009.03560.x.

21. Lodi S, Carpenter J, Egger P, Evans S. Design of cohort studies in chronic diseases using routinely collected databases when a prescription is used as surrogate outcome. BMC Med Res Methodol. 2011;11:36. Published 2011 Apr 1. doi:10.1186/1471-2288-11-36.

22. Curtis JR, Baddley JW, Yang S, Patkar N, Chen L, Delzell E, Mikuls TR, Saag KG, Singh J, Safford M, Cannon GW. Derivation and preliminary validation of an administrative claims-based algorithm for the effectiveness of medications for rheumatoid arthritis. Arthritis Res Ther. 2011;13(5):R155. doi: 10.1186/ar3471. Epub 2011 Sep 20. PMID: 21933396; PMCID: PMC3308085.

23. Leung J, Anderson TC, Dooling K, Xie F, Curtis JR. Recombinant Zoster Vaccine Uptake and Risk of Flares Among Older Adults With Immune-Mediated Inflammatory Diseases in the US. Arthritis Rheumatol. 2022 Jun 6. doi: 10.1002/art.42261.

24. Hua C, Buttgereit F, Combe B. Glucocorticoids in rheumatoid arthritis: current status and future studies. RMD Open. 2020 Jan;6(1):e000536. doi: 10.1136/rmdopen-2017-000536.

25. Yun H, Yang S, Chen L, Xie F, Winthrop K, Baddley JW, Saag KG, Singh J, Curtis JR. Risk of Herpes Zoster in Autoimmune and Inflammatory Diseases: Implications for Vaccination. Arthritis Rheumatol. 2016 Sep;68(9):2328-37. doi: 10.1002/art.39670.

26. Boutry C, Hastie A, Diez-Domingo J, et al. The Adjuvanted Recombinant Zoster Vaccine Confers Long-term Protection Against Herpes Zoster: Interim Results of an Extension Study of the Pivotal Phase III Clinical Trials (ZOE-50 and ZOE-70). Clin Infect Dis. Jul 20 2021;doi:10.1093/cid/ciab629.

27. Martin DO, Austin H. Exact estimates for a rate ratio. Epidemiology. Jan 1996;7(1):29-33. doi:10.1097/00001648-199601000-00006.

28. Kurth T, Seeger JD. Propensity score analysis in pharmacoepidemiology. Pharmacoepidemiology and Therapeutic Risk Management. Harvey Whitney Books; 2008.

29. McAfee AT, Ming EE, Seeger JD, et al. The comparative safety of rosuvastatin: a retrospective matched cohort study in over 48,000 initiators of statin therapy. Pharmacoepidemiol Drug Saf. Jul 2006;15(7):444-53. doi:10.1002/pds.1281.

30. Seeger JD, Loughlin J, Eng PM, Clifford CR, Cutone J, Walker AM. Risk of thromboembolism in women taking ethinylestradiol/drospirenone and other oral contraceptives. Obstet Gynecol. Sep 2007;110(3):587-93. doi:10.1097/01.AOG.0000279448.62221.a8.

31. Seeger JD. Exposure propensity scores. Post-Authorization Safety Studies of Medicinal Products: The PASS Book. Academic Press; 2018.

32. Austin, P.C. and E.A. Stuart. Moving towards best practice when using inverse probability of treatment weighting (IPTW) using the propensity score to estimate causal treatment effects in observational studies. Stat Med, 2015. 34(28): p. 3661-79.

33. Stürmer T, Wyss R, Glynn RJ, Brookhart MA. Propensity scores for confounder adjustment when assessing the effects of medical interventions using nonexperimental study designs. J Intern Med 2014 Jun;275(6):570-80.

34. Schneeweiss S. Sensitivity analysis and external adjustment for unmeasured confounders in epidemiologic database studies of therapeutics. Pharmacoepidemiol Drug Safety, 2006;15:291-303.

35. Dore DD, Bloomgren GL, Wenten M, et al. A cohort study of acute pancreatitis in relation to exenatide use. Diabetes Obes Metab 2011;13:559-66.

36. Eng PM, Mast TC, Loughlin J, Clifford CR, Wong J, Seeger JD. Incidence of intussusception among infants in a large commercially insured population in the United States. Pediatr Infect Dis J 2012;31:287-91.

37. Loughlin J, Quinn S, Rivero E, et al. Tegaserod and the risk of cardiovascular ischemic events: an observational cohort study. J Cardiovasc Pharmacol Ther 2010;15:151-7.

38. Quam L, Ellis LB, Venus P, Clouse J, Taylor CG, Leatherman S. Using claims data for epidemiologic research. The concordance of claims-based criteria with the medical record and patient survey for identifying a hypertensive population. Med Care 1993;31:498-507.

39. International Society of Pharmacoepidemiology Public Policy Committee. Guidelines for good pharmacoepidemiology practice (GPP). Pharmacoepidemiol Drug Saf 2016;25:2-10.

14. LIST OF TABLES

15. LIST OF FIGURES

ANNEX 1. LIST OF STAND ALONE DOCUMENTS

Number	Document reference number	Date	Title
1	Section 4	05 October 2023	Abstract: Observational Study of Effectiveness and Safety of Recombinant Zoster Vaccine (Shingrix)® in Moderately-to-Severely Active Ulcerative Colitis (UC) or Rheumatoid Arthritis (RA) Patients Treated with Tofacitinib (Xeljanz)® in Real-World Clinical Care Settings

ANNEX 2. ENCEPP CHECKLIST FOR STUDY PROTOCOLS

Not required.

ANNEX 3. ADDITIONAL INFORMATION

HCPCS, AHFS, NDC, CPT®[4] and ICD-10-PCS Codes for Secondary Outcomes

The following code lists will be used for the claims-based indicators of disease flare, as described in Section 9.3.5.2.

Codes for ulcerative colitis disease flare

Corticosteroids (oral, rectal, or injection)

Code type	Code	Description
HCPCS	J0702	INJECTION, BETAMETHASONE ACETATE 3MG AND BETAMETHASONE SODIUM PHOSPHATE 3MG
HCPCS	J0810	INJECTION, CORTISONE, UP TO 50 MG
HCPCS	J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG
HCPCS	J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG
HCPCS	J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG
HCPCS	J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG
HCPCS	J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG
HCPCS	J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG
HCPCS	J1700	INJECTION, HYDROCORTISONE ACETATE, UP TO 25 MG
HCPCS	J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, UP TO 50 MG
HCPCS	J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, UP TO 100 MG
HCPCS	J2650	INJECTION, PREDNISOLONE ACETATE, UP TO 1 ML
HCPCS	J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 40 MG
HCPCS	J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 125 MG
HCPCS	J3300	INJECTION, TRIAMCINOLONE ACETONIDE, PRESERVATIVE FREE, 1 MG
HCPCS	J3301	INJECTION, TRIAMCINOLONE ACETONIDE, NOT OTHERWISE SPECIFIED, 10 MG
HCPCS	J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5MG
HCPCS	J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5MG
HCPCS	J7506	PREDNISONE, ORAL, PER 5MG
HCPCS	J7509	METHYLPREDNISOLONE ORAL, PER 4 MG
HCPCS	J7510	PREDNISOLONE ORAL, PER 5 MG
HCPCS	J8540	DEXAMETHASONE, ORAL, 0.25 MG
HCPCS	J1095	INJECTION, DEXAMETHASONE ACETATE, PER 8 MG
HCPCS	J1690	INJECTION PREDNISONE, up to 20MG
HCPCS	J2640	INJECTION PREDNISLONE, up to 20MG
HCPCS	J3304	INJECT TRIAMCINOLONE ACETONIDE PF ER MS F 1 MG
HCPCS	J7312	INJECTION DEXAMETHASONE INTRAVITREAL IMPL
HCPCS	S0173	DEXAMETHASONE, ORAL, 4MG
HCPCS	J7512	Prednisone, immediate release or delayed release, oral
AHFS	680400	Adrenals*
AHFS	68040000	Adrenals*

* Restrict to those with oral, rectal, or injection routes of administration.

[4] CPT copyright 2022 American Medical Association. All rights reserved.

5-aminosalicylates (oral or rectal)

NDC	Description
43353088479	APRISO 0.375G CAP ER 24H
54868615000	APRISO 0.375G CAP.SR 24H
65649010302	APRISO 0.375G CAP.SR 24H
00149075206	ASACOL 400 MG TABLET DR
00430075227	ASACOL 400 MG TABLET DR
00149075202	ASACOL 400MG TABLET DR
00149075215	ASACOL 400MG TABLET DR
49999096918	ASACOL 400MG TABLET DR
54569479300	ASACOL 400MG TABLET DR
54868251500	ASACOL 400MG TABLET DR
54868251501	ASACOL 400MG TABLET DR
54868251502	ASACOL 400MG TABLET DR
54868251503	ASACOL 400MG TABLET DR
54868251504	ASACOL 400MG TABLET DR
54868251505	ASACOL 400MG TABLET DR
55289083330	ASACOL 400MG TABLET DR
67263005918	ASACOL 400MG TABLET DR
67544054981	ASACOL 400MG TABLET DR
67544054988	ASACOL 400MG TABLET DR
67544054989	ASACOL 400MG TABLET DR
68258912901	ASACOL 400MG TABLET DR
00023590118	ASACOL HD 800 MG TABLET DR
00430078327	ASACOL HD 800 MG TABLET DR
00149078301	ASACOL HD 800MG TABLET DR
42291015728	BALSALAZIDE DISODIUM 750 MG CAPSULE
50268010211	BALSALAZIDE DISODIUM 750 MG CAPSULE
50268010213	BALSALAZIDE DISODIUM 750 MG CAPSULE
54868613700	BALSALAZIDE DISODIUM 750 MG CAPSULE
55700027030	BALSALAZIDE DISODIUM 750 MG CAPSULE
60429095228	BALSALAZIDE DISODIUM 750 MG CAPSULE
68084079932	BALSALAZIDE DISODIUM 750 MG CAPSULE
68084079933	BALSALAZIDE DISODIUM 750 MG CAPSULE
68682075002	BALSALAZIDE DISODIUM 750 MG CAPSULE
72789014969	BALSALAZIDE DISODIUM 750 MG CAPSULE

NDC	Description
00054007928	BALSALAZIDE DISODIUM 750MG CAPSULE
00054007929	BALSALAZIDE DISODIUM 750MG CAPSULE
00378675082	BALSALAZIDE DISODIUM 750MG CAPSULE
00591357035	BALSALAZIDE DISODIUM 750MG CAPSULE
60505257507	BALSALAZIDE DISODIUM 750MG CAPSULE
67263044428	BALSALAZIDE DISODIUM 750MG CAPSULE
54868614700	CANASA 1000 MG SUPP.RECT
58914050101	CANASA 1000 MG SUPP.RECT
58914050118	CANASA 1000MG SUPP.RECT
58914050142	CANASA 1000MG SUPP.RECT
58914050156	CANASA 1000MG SUPP.RECT
54868519900	CANASA 500MG SUPP.RECT
58914050018	CANASA 500MG SUPP.RECT
58914050056	CANASA 500MG SUPP.RECT
54868485500	COLAZAL 750MG CAPSULE
65649010102	COLAZAL 750MG CAPSULE
65649010150	COLAZAL 750MG CAPSULE
00023585318	DELZICOL 400 MG CAP(DRTAB)
50090300200	DELZICOL 400 MG CAP(DRTAB)
00430075327	DELZICOL 400 MG CAPSULE DR
00016010501	DIPENTUM 250 MG CAPSULE
00037686010	DIPENTUM 250 MG CAPSULE
00013010501	DIPENTUM 250MG CAPSULE
00013010520	DIPENTUM 250MG CAPSULE
50474060001	DIPENTUM 250MG CAPSULE
50474060025	DIPENTUM 250MG CAPSULE
53014072671	DIPENTUM 250MG CAPSULE
53014072682	DIPENTUM 250MG CAPSULE
68220016010	DIPENTUM 250MG CAPSULE
00574725003	FIV-ASA 500 MG SUPP.RECT
65649010202	GIAZO 1.1 G TABLET
54092047601	LIALDA 1.2 G TABLET DR
54092047602	LIALDA 1.2 G TABLET DR
54092047612	LIALDA 1.2G TABLET DR
00378740178	MESALAMINE 1.2 G TABLET DR
00591224522	MESALAMINE 1.2 G TABLET DR
00904683204	MESALAMINE 1.2 G TABLET DR
16714083001	MESALAMINE 1.2 G TABLET DR

NDC	Description
42291056412	MESALAMINE 1.2 G TABLET DR
51407027412	MESALAMINE 1.2 G TABLET DR
54092010001	MESALAMINE 1.2 G TABLET DR
60687039725	MESALAMINE 1.2 G TABLET DR
60687039795	MESALAMINE 1.2 G TABLET DR
63304017513	MESALAMINE 1.2 G TABLET DR
68382071119	MESALAMINE 1.2 G TABLET DR
00378923093	MESALAMINE 1000 MG SUPP.RECT
00472191501	MESALAMINE 1000 MG SUPP.RECT
00472191530	MESALAMINE 1000 MG SUPP.RECT
00781708806	MESALAMINE 1000 MG SUPP.RECT
00781708833	MESALAMINE 1000 MG SUPP.RECT
16714024501	MESALAMINE 1000 MG SUPP.RECT
16714024530	MESALAMINE 1000 MG SUPP.RECT
31722000530	MESALAMINE 1000 MG SUPP.RECT
31722000532	MESALAMINE 1000 MG SUPP.RECT
59762011803	MESALAMINE 1000 MG SUPP.RECT
63629239701	MESALAMINE 1000 MG SUPP.RECT
64980028203	MESALAMINE 1000 MG SUPP.RECT
69238127403	MESALAMINE 1000 MG SUPP.RECT
69918056030	MESALAMINE 1000 MG SUPP.RECT
70710130206	MESALAMINE 1000 MG SUPP.RECT
70710130207	MESALAMINE 1000 MG SUPP.RECT
43386051081	MESALAMINE 4 G/60 ML ENEMA
50532006606	MESALAMINE 4 G/60 ML ENEMA
62559042007	MESALAMINE 4 G/60 ML ENEMA
62559042011	MESALAMINE 4 G/60 ML ENEMA
00093688871	MESALAMINE 4G/60ML ENEMA
43386051087	MESALAMINE 4G/60ML ENEMA
45802009828	MESALAMINE 4G/60ML ENEMA
45802009846	MESALAMINE 4G/60ML ENEMA
45802009851	MESALAMINE 4G/60ML ENEMA
54868531400	MESALAMINE 4G/60ML ENEMA
66993095077	MESALAMINE 4G/60ML ENEMA
60687026425	MESALAMINE 800 MG TABLET DR
60687026495	MESALAMINE 800 MG TABLET DR
60687034725	MESALAMINE 800 MG TABLET DR
60687034795	MESALAMINE 800 MG TABLET DR

NDC	Description
60687040825	MESALAMINE 800 MG TABLET DR
60687040895	MESALAMINE 800 MG TABLET DR
68382043528	MESALAMINE 800 MG TABLET DR
68382048428	MESALAMINE 800 MG TABLET DR
68382064928	MESALAMINE 800 MG TABLET DR
00093590786	MESALAMINE DR 400 MG CAP(DRTAB)
42291056318	MESALAMINE DR 400 MG CAP(DRTAB)
59762011701	MESALAMINE DR 400 MG CAP(DRTAB)
60687055632	MESALAMINE DR 400 MG CAP(DRTAB)
60687055633	MESALAMINE DR 400 MG CAP(DRTAB)
00093922489	MESALAMINE ER 0.375G CAP ER 24H
00378137578	MESALAMINE ER 0.375G CAP ER 24H
63629882701	MESALAMINE ER 0.375G CAP ER 24H
67877071712	MESALAMINE ER 0.375G CAP ER 24H
68382045219	MESALAMINE ER 0.375G CAP ER 24H
68682011320	MESALAMINE ER 0.375G CAP ER 24H
70748021416	MESALAMINE ER 0.375G CAP ER 24H
63304008913	MESALAMINE ER 500 MG CAPSULE ER
49452045003	MESALAMINE POWDER
49452045004	MESALAMINE POWDER
51927107800	MESALAMINE POWDER
62991270501	MESALAMINE POWDER
62991270502	MESALAMINE POWDER
62991270503	MESALAMINE POWDER
00088201046	PENTASA 250MG CAPSULE SA
00088201080	PENTASA 250MG CAPSULE SA
00088201090	PENTASA 250MG CAPSULE SA
54092018980	PENTASA 250MG CAPSULE SA
54092018981	PENTASA 250MG CAPSULE SA
54092019112	PENTASA 500MG CAPSULE SA
54092019180	PENTASA 500MG CAPSULE SA
54868530200	PENTASA 500MG CAPSULE SA
54868530201	PENTASA 500MG CAPSULE SA
00037006606	ROWASA 4 G/60 ML ENEMA
54569174301	ROWASA 4 G/60 ML ENEMA
00037006603	ROWASA 4 G/60 ML ENEMA KIT
00037006605	ROWASA 4 G/60 ML ENEMA KIT
00032192428	ROWASA 4G/60ML ENEMA

NDC	Description
00032192482	ROWASA 4G/60ML ENEMA
68220006607	ROWASA 4G/60ML ENEMA
68220006628	ROWASA 4G/60ML ENEMA
68220006603	ROWASA 4G/60ML KIT
68220006605	ROWASA 4G/60ML KIT
00032192824	ROWASA 500MG SUPP.RECT
00032192846	ROWASA 500MG SUPP.RECT
00037002207	SFROWASA 4 G/60 ML ENEMA
00037002228	SFROWASA 4 G/60 ML ENEMA
00037002260	SFROWASA 4 G/60 ML ENEMA
68220002260	SFROWASA 4 G/60 ML ENEMA
68220002207	SFROWASA 4G/60ML ENEMA
68220002214	SFROWASA 4G/60ML ENEMA
68220002228	SFROWASA 4G/60ML ENEMA
00574051501	5-AMINOSALICYLIC ACID POWDER
38779001204	5-AMINOSALICYLIC ACID POWDER
38779001205	5-AMINOSALICYLIC ACID POWDER
38779001208	5-AMINOSALICYLIC ACID POWDER
38779001210	5-AMINOSALICYLIC ACID POWDER
38779001225	5-AMINOSALICYLIC ACID POWDER
38779001250	5-AMINOSALICYLIC ACID POWDER
49452045001	5-AMINOSALICYLIC ACID POWDER
49452045002	5-AMINOSALICYLIC ACID POWDER
51552030204	5-AMINOSALICYLIC ACID POWDER
51552030205	5-AMINOSALICYLIC ACID POWDER
51552030206	5-AMINOSALICYLIC ACID POWDER
51552030225	5-AMINOSALICYLIC ACID POWDER
51552030250	5-AMINOSALICYLIC ACID POWDER
51552030299	5-AMINOSALICYLIC ACID POWDER
51552132604	5-AMINOSALICYLIC ACID POWDER
51552132605	5-AMINOSALICYLIC ACID POWDER
51552132606	5-AMINOSALICYLIC ACID POWDER
62991100901	5-AMINOSALICYLIC ACID POWDER
62991100902	5-AMINOSALICYLIC ACID POWDER
62991100903	5-AMINOSALICYLIC ACID POWDER
62991100904	5-AMINOSALICYLIC ACID POWDER

Immunosuppressants

Code Type	Code	Description
HCPCS	J7500	Azathioprine, oral, 50 mg
HCPCS	J7501	Azathioprine, parenteral, 100 mg
HCPCS	J7502	Cyclosporine, oral, 100 mg
HCPCS	J7515	Cyclosporine, oral, 25 mg
HCPCS	J7516	Cyclosporine, parenteral, 250 mg
HCPCS	S0108	Mercaptopurine, oral,50 mg
HCPCS	J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg
HCPCS	J7507	Tacrolimus, immediate release, oral, 1 mg
HCPCS	J7508	Tacrolimus, extended release, (Astagraf XL), oral, 0.1 mg
HCPCS	J7525	Tacrolimus, parenteral, 5 mg
NDC	00469064773	ASTAGRAF XL 0.5 MG CAP ER 24H
NDC	00469067773	ASTAGRAF XL 1 MG CAP ER 24H
NDC	00469068773	ASTAGRAF XL 5 MG CAP ER 24H
NDC	65649024141	AZASAN 100MG TABLET
NDC	66591024141	AZASAN 100MG TABLET
NDC	65649023141	AZASAN 75MG TABLET
NDC	66591023141	AZASAN 75MG TABLET
NDC	60219203701	AZATHIOPRINE 100 MG TABLET
NDC	68382012001	AZATHIOPRINE 100 MG TABLET
NDC	21695048475	AZATHIOPRINE 50 MG TABLET
NDC	42291007101	AZATHIOPRINE 50 MG TABLET
NDC	43353068609	AZATHIOPRINE 50 MG TABLET
NDC	43353068660	AZATHIOPRINE 50 MG TABLET
NDC	43353074509	AZATHIOPRINE 50 MG TABLET
NDC	43353074560	AZATHIOPRINE 50 MG TABLET
NDC	51079062001	AZATHIOPRINE 50 MG TABLET
NDC	51079062006	AZATHIOPRINE 50 MG TABLET
NDC	51407018201	AZATHIOPRINE 50 MG TABLET
NDC	54868531006	AZATHIOPRINE 50 MG TABLET
NDC	60219107601	AZATHIOPRINE 50 MG TABLET
NDC	67877049301	AZATHIOPRINE 50 MG TABLET
NDC	67877049305	AZATHIOPRINE 50 MG TABLET
NDC	69238107601	AZATHIOPRINE 50 MG TABLET
NDC	71610012409	AZATHIOPRINE 50 MG TABLET
NDC	71610030660	AZATHIOPRINE 50 MG TABLET
NDC	72789012930	AZATHIOPRINE 50 MG TABLET

Code Type	Code	Description
NDC	00054408425	AZATHIOPRINE 50MG TABLET
NDC	00054808425	AZATHIOPRINE 50MG TABLET
NDC	00378100501	AZATHIOPRINE 50MG TABLET
NDC	00406200301	AZATHIOPRINE 50MG TABLET
NDC	00781105901	AZATHIOPRINE 50MG TABLET
NDC	00781507501	AZATHIOPRINE 50MG TABLET
NDC	23490511009	AZATHIOPRINE 50MG TABLET
NDC	54868531000	AZATHIOPRINE 50MG TABLET
NDC	54868531001	AZATHIOPRINE 50MG TABLET
NDC	54868531002	AZATHIOPRINE 50MG TABLET
NDC	54868531003	AZATHIOPRINE 50MG TABLET
NDC	54868531004	AZATHIOPRINE 50MG TABLET
NDC	57866902101	AZATHIOPRINE 50MG TABLET
NDC	66479030110	AZATHIOPRINE 50MG TABLET
NDC	66591022141	AZATHIOPRINE 50MG TABLET
NDC	68084022901	AZATHIOPRINE 50MG TABLET
NDC	68084022911	AZATHIOPRINE 50MG TABLET
NDC	68382000301	AZATHIOPRINE 50MG TABLET
NDC	68382000305	AZATHIOPRINE 50MG TABLET
NDC	68462050201	AZATHIOPRINE 50MG TABLET
NDC	60219203601	AZATHIOPRINE 75 MG TABLET
NDC	68382011901	AZATHIOPRINE 75 MG TABLET
NDC	38779031203	AZATHIOPRINE POWDER
NDC	38779031204	AZATHIOPRINE POWDER
NDC	38779031206	AZATHIOPRINE POWDER
NDC	38779031211	AZATHIOPRINE POWDER
NDC	38779031215	AZATHIOPRINE POWDER
NDC	38779031225	AZATHIOPRINE POWDER
NDC	49452078201	AZATHIOPRINE POWDER
NDC	49452078202	AZATHIOPRINE POWDER
NDC	49452078203	AZATHIOPRINE POWDER
NDC	49452078301	AZATHIOPRINE POWDER
NDC	49452078302	AZATHIOPRINE POWDER
NDC	49452078303	AZATHIOPRINE POWDER
NDC	49452078304	AZATHIOPRINE POWDER
NDC	49452078305	AZATHIOPRINE POWDER
NDC	51552077902	AZATHIOPRINE POWDER
NDC	51552077904	AZATHIOPRINE POWDER

Code Type	Code	Description
NDC	51552077905	AZATHIOPRINE POWDER
NDC	51927225800	AZATHIOPRINE POWDER
NDC	52372072801	AZATHIOPRINE POWDER
NDC	52372072802	AZATHIOPRINE POWDER
NDC	52372072803	AZATHIOPRINE POWDER
NDC	52372072804	AZATHIOPRINE POWDER
NDC	62991218901	AZATHIOPRINE POWDER
NDC	62991218903	AZATHIOPRINE POWDER
NDC	62991218904	AZATHIOPRINE POWDER
NDC	00143956601	AZATHIOPRINE SODIUM 100 MG VIAL
NDC	51309022720	AZATHIOPRINE SODIUM 100 MG VIAL
NDC	55390060020	AZATHIOPRINE SODIUM 100MG VIAL
NDC	68084092125	CYCLOSPORINE 100 MG CAPSULE
NDC	68084092195	CYCLOSPORINE 100 MG CAPSULE
NDC	00172731246	CYCLOSPORINE 100MG CAPSULE
NDC	00185093330	CYCLOSPORINE 100MG CAPSULE
NDC	00591222315	CYCLOSPORINE 100MG CAPSULE
NDC	50111092043	CYCLOSPORINE 100MG CAPSULE
NDC	54868552200	CYCLOSPORINE 100MG CAPSULE
NDC	60505013400	CYCLOSPORINE 100MG CAPSULE
NDC	62584082711	CYCLOSPORINE 100MG CAPSULE
NDC	62584082721	CYCLOSPORINE 100MG CAPSULE
NDC	00172731320	CYCLOSPORINE 100MG/ML SOLUTION
NDC	00591222455	CYCLOSPORINE 100MG/ML SOLUTION
NDC	50111088542	CYCLOSPORINE 100MG/ML SOLUTION
NDC	60432014050	CYCLOSPORINE 100MG/ML SOLUTION
NDC	60505035401	CYCLOSPORINE 100MG/ML SOLUTION
NDC	68084087925	CYCLOSPORINE 25 MG CAPSULE
NDC	68084087995	CYCLOSPORINE 25 MG CAPSULE
NDC	00517086601	CYCLOSPORINE 250 MG/5ML AMPUL
NDC	00517086610	CYCLOSPORINE 250 MG/5ML AMPUL
NDC	00574086601	CYCLOSPORINE 250 MG/5ML AMPUL
NDC	00172731046	CYCLOSPORINE 25MG CAPSULE
NDC	00185093230	CYCLOSPORINE 25MG CAPSULE
NDC	00591222215	CYCLOSPORINE 25MG CAPSULE
NDC	50111090943	CYCLOSPORINE 25MG CAPSULE
NDC	60505013300	CYCLOSPORINE 25MG CAPSULE
NDC	00172731100	CYCLOSPORINE 50 MG CAPSULE

Code Type	Code	Description
NDC	00172731146	CYCLOSPORINE 50MG CAPSULE
NDC	00574086610	CYCLOSPORINE 50MG/ML AMPUL
NDC	55390012210	CYCLOSPORINE 50MG/ML VIAL
NDC	00093574219	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00093574265	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00093902019	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00093902065	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00172731200	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00185093386	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00185093387	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00591222354	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	51862046001	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	51862046047	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	54868623200	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	60505463203	CYCLOSPORINE MODIFIED 100 MG CAPSULE
NDC	00093574019	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00093574065	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00093901819	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00093901865	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00172731000	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00185093287	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	51862045801	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	51862045847	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	60505463003	CYCLOSPORINE MODIFIED 25 MG CAPSULE
NDC	00093574119	CYCLOSPORINE MODIFIED 50 MG CAPSULE
NDC	00093574165	CYCLOSPORINE MODIFIED 50 MG CAPSULE
NDC	00093901919	CYCLOSPORINE MODIFIED 50 MG CAPSULE
NDC	00093901965	CYCLOSPORINE MODIFIED 50 MG CAPSULE
NDC	60505463103	CYCLOSPORINE MODIFIED 50 MG CAPSULE
NDC	00395810819	CYCLOSPORINE POWDER
NDC	00395810835	CYCLOSPORINE POWDER
NDC	00395810862	CYCLOSPORINE POWDER
NDC	38779066001	CYCLOSPORINE POWDER
NDC	38779066003	CYCLOSPORINE POWDER
NDC	38779066004	CYCLOSPORINE POWDER
NDC	38779066005	CYCLOSPORINE POWDER
NDC	38779066006	CYCLOSPORINE POWDER
NDC	38779066008	CYCLOSPORINE POWDER

Code Type	Code	Description
NDC	46144032325	CYCLOSPORINE POWDER
NDC	49452241102	CYCLOSPORINE POWDER
NDC	51552066301	CYCLOSPORINE POWDER
NDC	51552066302	CYCLOSPORINE POWDER
NDC	51552066304	CYCLOSPORINE POWDER
NDC	51552066305	CYCLOSPORINE POWDER
NDC	51552066306	CYCLOSPORINE POWDER
NDC	51552066309	CYCLOSPORINE POWDER
NDC	51927319600	CYCLOSPORINE POWDER
NDC	62991153301	CYCLOSPORINE POWDER
NDC	62991153302	CYCLOSPORINE POWDER
NDC	62991153305	CYCLOSPORINE POWDER
NDC	63307013101	CYCLOSPORINE POWDER
NDC	63307013105	CYCLOSPORINE POWDER
NDC	63307013111	CYCLOSPORINE POWDER
NDC	63307013115	CYCLOSPORINE POWDER
NDC	63307013137	CYCLOSPORINE POWDER
NDC	63370005710	CYCLOSPORINE POWDER
NDC	70457982601	CYCLOSPORINE POWDER
NDC	70457982602	CYCLOSPORINE POWDER
NDC	70457982603	CYCLOSPORINE POWDER
NDC	71052042310	CYCLOSPORINE POWDER
NDC	71052042325	CYCLOSPORINE POWDER
NDC	68992307501	ENVARSUS XR 0.75 MG TAB ER 24H
NDC	68992307503	ENVARSUS XR 0.75 MG TAB ER 24H
NDC	68992301001	ENVARSUS XR 1 MG TAB ER 24H
NDC	68992301003	ENVARSUS XR 1 MG TAB ER 24H
NDC	68992304001	ENVARSUS XR 4 MG TAB ER 24H
NDC	68992304003	ENVARSUS XR 4 MG TAB ER 24H
NDC	00074310932	GENGRAF 100 MG CAPSULE
NDC	00074647932	GENGRAF 100MG CAPSULE
NDC	00074726950	GENGRAF 100MG/ML SOLUTION
NDC	00074310832	GENGRAF 25 MG CAPSULE
NDC	00074646332	GENGRAF 25MG CAPSULE
NDC	00074054130	GENGRAF 50 MG CAPSULE
NDC	00078061605	HECORIA 0.5 MG CAPSULE
NDC	00078061705	HECORIA 1 MG CAPSULE
NDC	00078061805	HECORIA 5 MG CAPSULE

Code Type	Code	Description
NDC	00081059871	IMURAN 100MG VIAL
NDC	00173059871	IMURAN 100MG VIAL
NDC	60976059871	IMURAN 100MG VIAL
NDC	65483055101	IMURAN 100MG VIAL
NDC	54569216900	IMURAN 50 MG TABLET
NDC	54569216901	IMURAN 50 MG TABLET
NDC	54766059010	IMURAN 50 MG TABLET
NDC	00081059755	IMURAN 50MG TABLET
NDC	00081059756	IMURAN 50MG TABLET
NDC	00173059755	IMURAN 50MG TABLET
NDC	52959007900	IMURAN 50MG TABLET
NDC	53002048600	IMURAN 50MG TABLET
NDC	54868092101	IMURAN 50MG TABLET
NDC	54868092102	IMURAN 50MG TABLET
NDC	54868092104	IMURAN 50MG TABLET
NDC	60976059755	IMURAN 50MG TABLET
NDC	65483059010	IMURAN 50MG TABLET
NDC	62991289901	MERCAPTOPURINE 100 % POWDER
NDC	62991289902	MERCAPTOPURINE 100 % POWDER
NDC	62991289903	MERCAPTOPURINE 100 % POWDER
NDC	38779142703	MERCAPTOPURINE 100% POWDER
NDC	38779142704	MERCAPTOPURINE 100% POWDER
NDC	38779142706	MERCAPTOPURINE 100% POWDER
NDC	49452446302	MERCAPTOPURINE 100% POWDER
NDC	51927200000	MERCAPTOPURINE 100% POWDER
NDC	54868528202	MERCAPTOPURINE 50 MG TABLET
NDC	68084032511	MERCAPTOPURINE 50 MG TABLET
NDC	68084032521	MERCAPTOPURINE 50 MG TABLET
NDC	69076091302	MERCAPTOPURINE 50 MG TABLET
NDC	69076091325	MERCAPTOPURINE 50 MG TABLET
NDC	00054458111	MERCAPTOPURINE 50MG TABLET
NDC	00054458127	MERCAPTOPURINE 50MG TABLET
NDC	00093551006	MERCAPTOPURINE 50MG TABLET
NDC	00378354725	MERCAPTOPURINE 50MG TABLET
NDC	00378354752	MERCAPTOPURINE 50MG TABLET
NDC	49884092202	MERCAPTOPURINE 50MG TABLET
NDC	49884092204	MERCAPTOPURINE 50MG TABLET
NDC	54868528200	MERCAPTOPURINE 50MG TABLET

Code Type	Code	Description
NDC	54868528201	MERCAPTOPURINE 50MG TABLET
NDC	68258910301	MERCAPTOPURINE 50MG TABLET
NDC	00078024861	NEORAL 100 MG CAPSULE
NDC	00078024815	NEORAL 100MG CAPSULE
NDC	00078027422	NEORAL 100MG/ML SOLUTION
NDC	00078024661	NEORAL 25 MG CAPSULE
NDC	00078024615	NEORAL 25MG CAPSULE
NDC	00469123050	PROGRAF 0.2 MG GRAN PACK
NDC	00469060767	PROGRAF 0.5MG CAPSULE
NDC	00469060773	PROGRAF 0.5MG CAPSULE
NDC	67263039601	PROGRAF 0.5MG CAPSULE
NDC	68258909901	PROGRAF 0.5MG CAPSULE
NDC	43353017809	PROGRAF 1 MG CAPSULE
NDC	00469133050	PROGRAF 1 MG GRAN PACK
NDC	21695017000	PROGRAF 1MG CAPSULE
NDC	00469061710	PROGRAF 1MG CAPSULE
NDC	00469061711	PROGRAF 1MG CAPSULE
NDC	00469061771	PROGRAF 1MG CAPSULE
NDC	00469061773	PROGRAF 1MG CAPSULE
NDC	67544120553	PROGRAF 1MG CAPSULE
NDC	67544120560	PROGRAF 1MG CAPSULE
NDC	67544120580	PROGRAF 1MG CAPSULE
NDC	00469065710	PROGRAF 5MG CAPSULE
NDC	00469065711	PROGRAF 5MG CAPSULE
NDC	00469065771	PROGRAF 5MG CAPSULE
NDC	00469065773	PROGRAF 5MG CAPSULE
NDC	00469301601	PROGRAF 5MG/ML AMPUL
NDC	00081080725	PURINETHOL 50MG TABLET
NDC	00081080765	PURINETHOL 50MG TABLET
NDC	00173080725	PURINETHOL 50MG TABLET
NDC	00173080765	PURINETHOL 50MG TABLET
NDC	57844052206	PURINETHOL 50MG TABLET
NDC	57844052207	PURINETHOL 50MG TABLET
NDC	57844052252	PURINETHOL 50MG TABLET
NDC	60311045001	PURIXAN 20 MG/ML ORAL SUSP
NDC	62484000202	PURIXAN 20 MG/ML ORAL SUSP
NDC	62484002001	PURIXAN 20 MG/ML ORAL SUSP
NDC	62484002002	PURIXAN 20 MG/ML ORAL SUSP

Code Type	Code	Description
NDC	00078024161	SANDIMMUNE 100 MG CAPSULE
NDC	00078024115	SANDIMMUNE 100MG CAPSULE
NDC	54569287200	SANDIMMUNE 100MG CAPSULE
NDC	00078011022	SANDIMMUNE 100MG/ML SOLUTION
NDC	54569256300	SANDIMMUNE 100MG/ML SOLUTION
NDC	00078024061	SANDIMMUNE 25 MG CAPSULE
NDC	00078010961	SANDIMMUNE 250 MG/5ML AMPUL
NDC	00078024015	SANDIMMUNE 25MG CAPSULE
NDC	54569287300	SANDIMMUNE 25MG CAPSULE
NDC	00078024215	SANDIMMUNE 50MG CAPSULE
NDC	00078010901	SANDIMMUNE 50MG/ML AMPUL
NDC	16714009801	TACROLIMUS 0.5 MG CAPSULE
NDC	16729004101	TACROLIMUS 0.5 MG CAPSULE
NDC	00378204501	TACROLIMUS 0.5 MG CAPSULE
NDC	00378204505	TACROLIMUS 0.5 MG CAPSULE
NDC	42291075201	TACROLIMUS 0.5 MG CAPSULE
NDC	50742020701	TACROLIMUS 0.5 MG CAPSULE
NDC	51079081701	TACROLIMUS 0.5 MG CAPSULE
NDC	51079081720	TACROLIMUS 0.5 MG CAPSULE
NDC	55111052501	TACROLIMUS 0.5 MG CAPSULE
NDC	60429037701	TACROLIMUS 0.5 MG CAPSULE
NDC	62175038037	TACROLIMUS 0.5 MG CAPSULE
NDC	63629872501	TACROLIMUS 0.5 MG CAPSULE
NDC	64380072006	TACROLIMUS 0.5 MG CAPSULE
NDC	67877027801	TACROLIMUS 0.5 MG CAPSULE
NDC	68084044901	TACROLIMUS 0.5 MG CAPSULE
NDC	68084044911	TACROLIMUS 0.5 MG CAPSULE
NDC	68462068501	TACROLIMUS 0.5 MG CAPSULE
NDC	69452015320	TACROLIMUS 0.5 MG CAPSULE
NDC	70377001411	TACROLIMUS 0.5 MG CAPSULE
NDC	70748021901	TACROLIMUS 0.5 MG CAPSULE
NDC	72572076001	TACROLIMUS 0.5 MG CAPSULE
NDC	00781930201	TACROLIMUS 0.5 MG CAPSULE
NDC	00904662361	TACROLIMUS 0.5 MG CAPSULE
NDC	16714009901	TACROLIMUS 1 MG CAPSULE
NDC	16729004201	TACROLIMUS 1 MG CAPSULE
NDC	00378204601	TACROLIMUS 1 MG CAPSULE
NDC	00378204605	TACROLIMUS 1 MG CAPSULE

Code Type	Code	Description
NDC	42291075301	TACROLIMUS 1 MG CAPSULE
NDC	43353017853	TACROLIMUS 1 MG CAPSULE
NDC	43353017860	TACROLIMUS 1 MG CAPSULE
NDC	43353017880	TACROLIMUS 1 MG CAPSULE
NDC	43353031709	TACROLIMUS 1 MG CAPSULE
NDC	43353031716	TACROLIMUS 1 MG CAPSULE
NDC	43353031753	TACROLIMUS 1 MG CAPSULE
NDC	43353031770	TACROLIMUS 1 MG CAPSULE
NDC	43353031780	TACROLIMUS 1 MG CAPSULE
NDC	50090224500	TACROLIMUS 1 MG CAPSULE
NDC	50090559600	TACROLIMUS 1 MG CAPSULE
NDC	50742020801	TACROLIMUS 1 MG CAPSULE
NDC	51079081801	TACROLIMUS 1 MG CAPSULE
NDC	51079081820	TACROLIMUS 1 MG CAPSULE
NDC	54288013201	TACROLIMUS 1 MG CAPSULE
NDC	54288013501	TACROLIMUS 1 MG CAPSULE
NDC	55111052601	TACROLIMUS 1 MG CAPSULE
NDC	60429037801	TACROLIMUS 1 MG CAPSULE
NDC	62175038137	TACROLIMUS 1 MG CAPSULE
NDC	63629872301	TACROLIMUS 1 MG CAPSULE
NDC	64380072106	TACROLIMUS 1 MG CAPSULE
NDC	67877027901	TACROLIMUS 1 MG CAPSULE
NDC	68084045001	TACROLIMUS 1 MG CAPSULE
NDC	68084045011	TACROLIMUS 1 MG CAPSULE
NDC	68462068601	TACROLIMUS 1 MG CAPSULE
NDC	69452015420	TACROLIMUS 1 MG CAPSULE
NDC	70377001511	TACROLIMUS 1 MG CAPSULE
NDC	70748022001	TACROLIMUS 1 MG CAPSULE
NDC	72572076101	TACROLIMUS 1 MG CAPSULE
NDC	00781930301	TACROLIMUS 1 MG CAPSULE
NDC	00904642561	TACROLIMUS 1 MG CAPSULE
NDC	00904709761	TACROLIMUS 1 MG CAPSULE
NDC	10695008521	TACROLIMUS 100 % POWDER
NDC	38779227209	TACROLIMUS 100 % POWDER
NDC	38779269800	TACROLIMUS 100 % POWDER
NDC	38779269803	TACROLIMUS 100 % POWDER
NDC	38779269804	TACROLIMUS 100 % POWDER
NDC	38779269806	TACROLIMUS 100 % POWDER

Code Type	Code	Description
NDC	38779269807	TACROLIMUS 100 % POWDER
NDC	38779269809	TACROLIMUS 100 % POWDER
NDC	51552140302	TACROLIMUS 100 % POWDER
NDC	51552140303	TACROLIMUS 100 % POWDER
NDC	51927492400	TACROLIMUS 100 % POWDER
NDC	52372060901	TACROLIMUS 100 % POWDER
NDC	52372060902	TACROLIMUS 100 % POWDER
NDC	52372060903	TACROLIMUS 100 % POWDER
NDC	58597802901	TACROLIMUS 100 % POWDER
NDC	58597802902	TACROLIMUS 100 % POWDER
NDC	58597802903	TACROLIMUS 100 % POWDER
NDC	58597802904	TACROLIMUS 100 % POWDER
NDC	58597802905	TACROLIMUS 100 % POWDER
NDC	58597802906	TACROLIMUS 100 % POWDER
NDC	62991266401	TACROLIMUS 100 % POWDER
NDC	62991266402	TACROLIMUS 100 % POWDER
NDC	62991266403	TACROLIMUS 100 % POWDER
NDC	62991266404	TACROLIMUS 100 % POWDER
NDC	62991307201	TACROLIMUS 100 % POWDER
NDC	62991307202	TACROLIMUS 100 % POWDER
NDC	62991307203	TACROLIMUS 100 % POWDER
NDC	62991307204	TACROLIMUS 100 % POWDER
NDC	71052005801	TACROLIMUS 100 % POWDER
NDC	71052005802	TACROLIMUS 100 % POWDER
NDC	38779227200	TACROLIMUS 100% POWDER
NDC	38779227203	TACROLIMUS 100% POWDER
NDC	38779227204	TACROLIMUS 100% POWDER
NDC	38779227206	TACROLIMUS 100% POWDER
NDC	51552112801	TACROLIMUS 100% POWDER
NDC	51552112804	TACROLIMUS 100% POWDER
NDC	51552112805	TACROLIMUS 100% POWDER
NDC	51552112806	TACROLIMUS 100% POWDER
NDC	51927355700	TACROLIMUS 100% POWDER
NDC	16714010001	TACROLIMUS 5 MG CAPSULE
NDC	16729004301	TACROLIMUS 5 MG CAPSULE
NDC	00378204701	TACROLIMUS 5 MG CAPSULE
NDC	00378204705	TACROLIMUS 5 MG CAPSULE
NDC	42291075401	TACROLIMUS 5 MG CAPSULE

Code Type	Code	Description
NDC	50742020901	TACROLIMUS 5 MG CAPSULE
NDC	51079002801	TACROLIMUS 5 MG CAPSULE
NDC	51079002820	TACROLIMUS 5 MG CAPSULE
NDC	55111052701	TACROLIMUS 5 MG CAPSULE
NDC	00591335901	TACROLIMUS 5 MG CAPSULE
NDC	60429037901	TACROLIMUS 5 MG CAPSULE
NDC	62175038237	TACROLIMUS 5 MG CAPSULE
NDC	63629872601	TACROLIMUS 5 MG CAPSULE
NDC	64380072206	TACROLIMUS 5 MG CAPSULE
NDC	67877028001	TACROLIMUS 5 MG CAPSULE
NDC	68084045101	TACROLIMUS 5 MG CAPSULE
NDC	68084045111	TACROLIMUS 5 MG CAPSULE
NDC	68462068701	TACROLIMUS 5 MG CAPSULE
NDC	69452015520	TACROLIMUS 5 MG CAPSULE
NDC	70377001611	TACROLIMUS 5 MG CAPSULE
NDC	70748022101	TACROLIMUS 5 MG CAPSULE
NDC	00781930401	TACROLIMUS 5 MG CAPSULE
NDC	00904662461	TACROLIMUS 5 MG CAPSULE
NDC	00781210201	TACROLIMUS ANHYDROUS 0.5MG CAPSULE
NDC	00781210301	TACROLIMUS ANHYDROUS 1MG CAPSULE
NDC	00781210401	TACROLIMUS ANHYDROUS 5MG CAPSULE
NDC	63275995801	TACROLIMUS MICRONIZED 100% POWDER
NDC	63275995802	TACROLIMUS MICRONIZED 100% POWDER
NDC	63275995806	TACROLIMUS MICRONIZED 100% POWDER
NDC	63275995807	TACROLIMUS MICRONIZED 100% POWDER

Emergency room visit with UC as primary diagnosis

Emergency room visits associated with a diagnosis of UC (ICD-10 code: K51*) will be identified based on the presence of evaluation and management codes associated with emergency department visits and place of service codes.

Hospitalization with UC as primary diagnosis

Hospitalizations associated with a diagnosis of UC (ICD-10 code: K51*) will be identified based on revenue codes, place of service codes, and provider specialty.

UC-related surgery

Code Type	Code	Description
CPT®[5]	44139	Mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)
CPT	44140	Colectomy, partial; with anastomosis
CPT	44141	Colectomy, partial; with skin level cecostomy or colostomy
CPT	44143	Colectomy, partial; with end colostomy and closure of distal segment (Hartmann type procedure)
CPT	44144	Colectomy, partial; with resection, with colostomy or ileostomy and creation of mucofistula
CPT	44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)
CPT	44146	Colectomy, partial; with coloproctostomy (low pelvic anastomosis), with colostomy
CPT	44147	Colectomy, partial; abdominal and transanal approach
CPT	44150	Colectomy, total, abdominal, without proctectomy; with ileostomy or ileoproctostomy
CPT	44151	Colectomy, total, abdominal, without proctectomy; with continent ileostomy
CPT	44155	Colectomy, total, abdominal, with proctectomy; with ileostomy
CPT	44156	Colectomy, total, abdominal, with proctectomy; with continent ileostomy
CPT	44157	Colectomy, total, abdominal, with proctectomy; with ileoanal anastomosis, includes loop ileostomy, and rectal mucosectomy, when performed
CPT	44158	Colectomy, total, abdominal, with proctectomy; with ileoanal anastomosis, creation of ileal reservoir (S or J), includes loop ileostomy, and rectal mucosectomy, when performed
CPT	44160	Colectomy, partial, with removal of terminal ileum with ileocolostomy
CPT	44204	Laparoscopy, surgical; colectomy, partial, with anastomosis
CPT	44205	Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy
CPT	44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)
CPT	44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)
CPT	44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy
CPT	44210	Laparoscopy, surgical; colectomy, total, abdominal, without proctectomy, with ileostomy or ileoproctostomy
CPT	44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (S or J), with loop ileostomy, includes rectal mucosectomy, when performed
CPT	44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy
CPT	44213	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)

[5] CPT copyright 2022 American Medical Association. All rights reserved.

Code Type	Code	Description
CPT[6]	45121	Proctectomy, complete (for congenital megacolon), abdominal and perineal approach; with subtotal or total colectomy, with multiple biopsies
ICD-10-PCS	0DBE0ZZ	Excision of Large Intestine, Open Approach
ICD-10-PCS	0DBE3ZZ	Excision of Large Intestine, Percutaneous Approach
ICD-10-PCS	0DBE4ZZ	Excision of Large Intestine, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBE7ZZ	Excision of Large Intestine, Via Natural or Artificial Opening
ICD-10-PCS	0DBE8ZZ	Excision of Large Intestine, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBF0ZZ	Excision of Right Large Intestine, Open Approach
ICD-10-PCS	0DBF3ZZ	Excision of Right Large Intestine, Percutaneous Approach
ICD-10-PCS	0DBF4ZZ	Excision of Right Large Intestine, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBF7ZZ	Excision of Right Large Intestine, Via Natural or Artificial Opening
ICD-10-PCS	0DBF8ZZ	Excision of Right Large Intestine, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBG0ZZ	Excision of Left Large Intestine, Open Approach
ICD-10-PCS	0DBG3ZZ	Excision of Left Large Intestine, Percutaneous Approach
ICD-10-PCS	0DBG4ZZ	Excision of Left Large Intestine, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBG7ZZ	Excision of Left Large Intestine, Via Natural or Artificial Opening
ICD-10-PCS	0DBG8ZZ	Excision of Left Large Intestine, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBK0ZZ	Excision of Ascending Colon, Open Approach
ICD-10-PCS	0DBK3ZZ	Excision of Ascending Colon, Percutaneous Approach
ICD-10-PCS	0DBK4ZZ	Excision of Ascending Colon, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBK7ZZ	Excision of Ascending Colon, Via Natural or Artificial Opening
ICD-10-PCS	0DBK8ZZ	Excision of Ascending Colon, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBL0ZZ	Excision of Transverse Colon, Open Approach
ICD-10-PCS	0DBL3ZZ	Excision of Transverse Colon, Percutaneous Approach
ICD-10-PCS	0DBL4ZZ	Excision of Transverse Colon, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBL7ZZ	Excision of Transverse Colon, Via Natural or Artificial Opening
ICD-10-PCS	0DBL8ZZ	Excision of Transverse Colon, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBLFZZ	Excision of Transverse Colon, Via Natural or Artificial Opening With Percutaneous Endoscopic Assistance
ICD-10-PCS	0DBM0ZZ	Excision of Descending Colon, Open Approach
ICD-10-PCS	0DBM3ZZ	Excision of Descending Colon, Percutaneous Approach
ICD-10-PCS	0DBM4ZZ	Excision of Descending Colon, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBM7ZZ	Excision of Descending Colon, Via Natural or Artificial Opening
ICD-10-PCS	0DBM8ZZ	Excision of Descending Colon, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DBN0ZZ	Excision of Sigmoid Colon, Open Approach
ICD-10-PCS	0DBN3ZZ	Excision of Sigmoid Colon, Percutaneous Approach

[6] CPT copyright 2022 American Medical Association. All rights reserved.

Code Type	Code	Description
ICD-10-PCS	0DBN4ZZ	Excision of Sigmoid Colon, Percutaneous Endoscopic Approach
ICD-10-PCS	0DBN7ZZ	Excision of Sigmoid Colon, Via Natural or Artificial Opening
ICD-10-PCS	0DBN8ZZ	Excision of Sigmoid Colon, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DTE0ZZ	Resection of Large Intestine, Open Approach
ICD-10-PCS	0DTE4ZZ	Resection of Large Intestine, Percutaneous Endoscopic Approach
ICD-10-PCS	0DTE7ZZ	Resection of Large Intestine, Via Natural or Artificial Opening
ICD-10-PCS	0DTE8ZZ	Resection of Large Intestine, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DTP0ZZ	Resection of Rectum, Open Approach
ICD-10-PCS	0DTP4ZZ	Resection of Rectum, Percutaneous Endoscopic Approach
ICD-10-PCS	0DTP7ZZ	Resection of Rectum, Via Natural or Artificial Opening
ICD-10-PCS	0DTP8ZZ	Resection of Rectum, Via Natural or Artificial Opening Endoscopic

Codes for rheumatoid arthritis disease flare

Corticosteroids (oral or injection)

Code type	Code	Description
HCPCS	J0702	INJECTION, BETAMETHASONE ACETATE 3MG AND BETAMETHASONE SODIUM PHOSPHATE 3MG
HCPCS	J0810	INJECTION, CORTISONE, UP TO 50 MG
HCPCS	J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG
HCPCS	J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG
HCPCS	J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG
HCPCS	J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG
HCPCS	J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG
HCPCS	J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG
HCPCS	J1700	INJECTION, HYDROCORTISONE ACETATE, UP TO 25 MG
HCPCS	J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, UP TO 50 MG
HCPCS	J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, UP TO 100 MG
HCPCS	J2650	INJECTION, PREDNISOLONE ACETATE, UP TO 1 ML
HCPCS	J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 40 MG
HCPCS	J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, UP TO 125 MG
HCPCS	J3300	INJECTION, TRIAMCINOLONE ACETONIDE, PRESERVATIVE FREE, 1 MG
HCPCS	J3301	INJECTION, TRIAMCINOLONE ACETONIDE, NOT OTHERWISE SPECIFIED, 10 MG
HCPCS	J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5MG
HCPCS	J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5MG
HCPCS	J7506	PREDNISONE, ORAL, PER 5MG
HCPCS	J7509	METHYLPREDNISOLONE ORAL, PER 4 MG
HCPCS	J7510	PREDNISOLONE ORAL, PER 5 MG
HCPCS	J8540	DEXAMETHASONE, ORAL, 0.25 MG
HCPCS	J1095	INJECTION, DEXAMETHASONE ACETATE, PER 8 MG
HCPCS	J1690	INJECTION PREDNISONE, up to 20MG
HCPCS	J2640	INJECTION PREDNISLONE, up to 20MG
HCPCS	J3304	INJECT TRIAMCINOLONE ACETONIDE PF ER MS F 1 MG
HCPCS	J7312	INJECTION DEXAMETHASONE INTRAVITREAL IMPL

Code type	Code	Description
HCPCS	S0173	DEXAMETHASONE, ORAL, 4MG
HCPCS	J7512	Prednisone, immediate release or delayed release, oral
AHFS	680400	Adrenals*
AHFS	68040000	Adrenals*

*Restrict to those with oral or injection routes of administration.

csDMARDs

Code Type	Code	Description
HCPCS	J9250	Methotrexate sodium, 5 mg
HCPCS	J9260	Methotrexate sodium, 50 mg
HCPCS	J8610	Methotrexate, oral, 2.5 mg
NDC	53443000321	ABITREXATE 25 MG/ML VIAL
NDC	53443000322	ABITREXATE 25 MG/ML VIAL
NDC	53443000324	ABITREXATE 25 MG/ML VIAL
NDC	00088216203	ARAVA 100MG TABLET
NDC	54868490200	ARAVA 10MG TABLET
NDC	00088216030	ARAVA 10MG TABLET
NDC	54868438500	ARAVA 20MG TABLET
NDC	68115081730	ARAVA 20MG TABLET
NDC	00088216130	ARAVA 20MG TABLET
NDC	00013010110	AZULFIDINE 500 MG TABLET
NDC	00013010130	AZULFIDINE 500 MG TABLET
NDC	00016010101	AZULFIDINE 500 MG TABLET
NDC	00016010105	AZULFIDINE 500 MG TABLET
NDC	00016010110	AZULFIDINE 500 MG TABLET
NDC	00016010111	AZULFIDINE 500 MG TABLET
NDC	54569007200	AZULFIDINE 500 MG TABLET
NDC	54569007201	AZULFIDINE 500 MG TABLET
NDC	00013010250	AZULFIDINE 500 MG TABLET DR
NDC	00013010260	AZULFIDINE 500 MG TABLET DR
NDC	00016010201	AZULFIDINE 500 MG TABLET DR
NDC	00016010205	AZULFIDINE 500 MG TABLET DR
NDC	00013010101	AZULFIDINE 500MG TABLET
NDC	00013010105	AZULFIDINE 500MG TABLET
NDC	00013010111	AZULFIDINE 500MG TABLET
NDC	00013010120	AZULFIDINE 500MG TABLET
NDC	54868112301	AZULFIDINE 500MG TABLET
NDC	00013010201	AZULFIDINE 500MG TABLET DR

Code Type	Code	Description
NDC	00013010205	AZULFIDINE 500MG TABLET DR
NDC	00013010220	AZULFIDINE 500MG TABLET DR
NDC	00013229686	FOLEX PFS 25 MG/ML VIAL
NDC	00013229691	FOLEX PFS 25MG/ML VIAL
NDC	00013226686	FOLEX-PFS 25 MG/ML VIAL
NDC	00013227686	FOLEX-PFS 25 MG/ML VIAL
NDC	00013228686	FOLEX-PFS 25 MG/ML VIAL
NDC	00013226691	FOLEX-PFS 25MG/ML VIAL
NDC	00013227691	FOLEX-PFS 25MG/ML VIAL
NDC	00013228691	FOLEX-PFS 25MG/ML VIAL
NDC	16729056101	HYDROXYCHLOROQUINE SULFATE 100 MG TABLET
NDC	10544057890	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16571068701	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16571068750	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16714011001	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16714011002	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16714047401	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16714075301	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16729048501	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	16729048516	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	21695048630	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00378037399	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42291031801	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42291031818	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42291032001	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42291032018	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42292001101	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42292001106	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42385092701	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	42385092705	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353005109	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353005153	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353005160	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353010309	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353010353	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353010360	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353010380	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353076153	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET

Code Type	Code	Description
NDC	43353076180	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353079416	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353079453	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353079460	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353079480	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353097209	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353097253	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43353097260	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43598072101	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	43598072105	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	47463301730	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	50090250801	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	50090343201	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	50268041211	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	50268041215	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	51660029601	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	57664076113	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	57664076188	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00591304101	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00591304105	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	59746078001	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	59746078005	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	60429070001	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	61919013230	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	63629242501	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	63629334301	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	63739077710	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	66993005702	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	66993005704	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	69238154401	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610004709	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610004730	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610004753	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610004760	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610004780	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610050630	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610050653	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	71610050730	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET

Code Type	Code	Description
NDC	71610050753	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	72189008530	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	72789002601	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	76385014401	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	76385014450	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00781140752	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00781140797	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00781599401	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00781599405	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904650806	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904650861	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904688406	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904688461	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904704606	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00904704661	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00093240101	HYDROXYCHLOROQUINE SULFATE 200 MG TABLET
NDC	00143212801	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	17236061001	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	17236061005	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00182260901	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	23490572403	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	23490572406	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	23490572409	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	23629002601	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	23629002610	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00364262701	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00378037301	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	38245077410	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	38245077450	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00406209601	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00406209605	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00440761530	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	49999037260	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	51875037701	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	51875037702	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	52544069801	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	52544069805	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	52555064201	HYDROXYCHLOROQUINE SULFATE 200MG TABLET

Code Type	Code	Description
NDC	52959017660	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00536571001	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54569498100	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54569498101	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54868382100	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54868382101	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54868382102	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	54868382103	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	55175503101	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	55887091601	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	57866902701	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00591069801	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00591069805	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00603394421	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	60429070030	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	60429070060	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	62269025024	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	62269025029	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	63304029601	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	63304029605	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	65162061010	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	65243025518	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	67544098180	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00677159001	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68084026901	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68084026911	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68115063300	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68258906301	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68382009601	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	68382009605	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00781140701	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00781140705	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00839796306	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00904510760	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00093977401	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00093977405	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00955079001	HYDROXYCHLOROQUINE SULFATE 200MG TABLET
NDC	00955079005	HYDROXYCHLOROQUINE SULFATE 200MG TABLET

Code Type	Code	Description
NDC	16729056201	HYDROXYCHLOROQUINE SULFATE 300 MG TABLET
NDC	16729056301	HYDROXYCHLOROQUINE SULFATE 400 MG TABLET
NDC	38779135205	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452006401	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362501	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362502	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362503	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362504	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362505	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	49452362506	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	51927213600	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	63370010425	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	63370010435	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	63370010445	HYDROXYCHLOROQUINE SULFATE POWDER
NDC	10702027703	LEFLUNOMIDE 10 MG TABLET
NDC	13811067730	LEFLUNOMIDE 10 MG TABLET
NDC	16714032101	LEFLUNOMIDE 10 MG TABLET
NDC	23155004303	LEFLUNOMIDE 10 MG TABLET
NDC	35573044730	LEFLUNOMIDE 10 MG TABLET
NDC	42291042030	LEFLUNOMIDE 10 MG TABLET
NDC	50268047711	LEFLUNOMIDE 10 MG TABLET
NDC	50268047715	LEFLUNOMIDE 10 MG TABLET
NDC	54868617000	LEFLUNOMIDE 10 MG TABLET
NDC	59651034830	LEFLUNOMIDE 10 MG TABLET
NDC	60429031930	LEFLUNOMIDE 10 MG TABLET
NDC	62332006130	LEFLUNOMIDE 10 MG TABLET
NDC	70710115703	LEFLUNOMIDE 10 MG TABLET
NDC	70748012906	LEFLUNOMIDE 10 MG TABLET
NDC	00955173530	LEFLUNOMIDE 10 MG TABLET
NDC	71052026010	LEFLUNOMIDE 100 % POWDER
NDC	71052026025	LEFLUNOMIDE 100 % POWDER
NDC	49884088805	LEFLUNOMIDE 10MG TABLET
NDC	49884088811	LEFLUNOMIDE 10MG TABLET
NDC	00555035101	LEFLUNOMIDE 10MG TABLET
NDC	60505250201	LEFLUNOMIDE 10MG TABLET
NDC	60505250203	LEFLUNOMIDE 10MG TABLET
NDC	66993016030	LEFLUNOMIDE 10MG TABLET
NDC	00781505631	LEFLUNOMIDE 10MG TABLET

Code Type	Code	Description
NDC	00093017356	LEFLUNOMIDE 10MG TABLET
NDC	10702027803	LEFLUNOMIDE 20 MG TABLET
NDC	13811067830	LEFLUNOMIDE 20 MG TABLET
NDC	16714033101	LEFLUNOMIDE 20 MG TABLET
NDC	23155004403	LEFLUNOMIDE 20 MG TABLET
NDC	35573044830	LEFLUNOMIDE 20 MG TABLET
NDC	42291042130	LEFLUNOMIDE 20 MG TABLET
NDC	50090599200	LEFLUNOMIDE 20 MG TABLET
NDC	50268047811	LEFLUNOMIDE 20 MG TABLET
NDC	50268047815	LEFLUNOMIDE 20 MG TABLET
NDC	59651034930	LEFLUNOMIDE 20 MG TABLET
NDC	60429032030	LEFLUNOMIDE 20 MG TABLET
NDC	62332006230	LEFLUNOMIDE 20 MG TABLET
NDC	63629126301	LEFLUNOMIDE 20 MG TABLET
NDC	70710115803	LEFLUNOMIDE 20 MG TABLET
NDC	70748013006	LEFLUNOMIDE 20 MG TABLET
NDC	00955173730	LEFLUNOMIDE 20 MG TABLET
NDC	49884088905	LEFLUNOMIDE 20MG TABLET
NDC	49884088911	LEFLUNOMIDE 20MG TABLET
NDC	54868231900	LEFLUNOMIDE 20MG TABLET
NDC	00555035201	LEFLUNOMIDE 20MG TABLET
NDC	60505250301	LEFLUNOMIDE 20MG TABLET
NDC	60505250303	LEFLUNOMIDE 20MG TABLET
NDC	66993016130	LEFLUNOMIDE 20MG TABLET
NDC	00781505731	LEFLUNOMIDE 20MG TABLET
NDC	00093017456	LEFLUNOMIDE 20MG TABLET
NDC	00143936701	METHOTREXATE 1 G VIAL
NDC	00143983001	METHOTREXATE 1 G VIAL
NDC	63323012259	METHOTREXATE 1 G VIAL
NDC	62991120004	METHOTREXATE 100 % POWDER
NDC	49452460101	METHOTREXATE 100% POWDER
NDC	49452460102	METHOTREXATE 100% POWDER
NDC	49452460103	METHOTREXATE 100% POWDER
NDC	49452460104	METHOTREXATE 100% POWDER
NDC	55390014301	METHOTREXATE 1G VIAL
NDC	63323012250	METHOTREXATE 1G VIAL
NDC	16729048601	METHOTREXATE 2.5 MG TABLET
NDC	00182153989	METHOTREXATE 2.5 MG TABLET

Code Type	Code	Description
NDC	21695011130	METHOTREXATE 2.5 MG TABLET
NDC	42254011030	METHOTREXATE 2.5 MG TABLET
NDC	42291050501	METHOTREXATE 2.5 MG TABLET
NDC	42291059401	METHOTREXATE 2.5 MG TABLET
NDC	43063043930	METHOTREXATE 2.5 MG TABLET
NDC	47335023583	METHOTREXATE 2.5 MG TABLET
NDC	47335023596	METHOTREXATE 2.5 MG TABLET
NDC	47781048201	METHOTREXATE 2.5 MG TABLET
NDC	49999038036	METHOTREXATE 2.5 MG TABLET
NDC	50090029409	METHOTREXATE 2.5 MG TABLET
NDC	50090234509	METHOTREXATE 2.5 MG TABLET
NDC	50090341802	METHOTREXATE 2.5 MG TABLET
NDC	50268052711	METHOTREXATE 2.5 MG TABLET
NDC	50268052715	METHOTREXATE 2.5 MG TABLET
NDC	51407012101	METHOTREXATE 2.5 MG TABLET
NDC	51432052203	METHOTREXATE 2.5 MG TABLET
NDC	54569181801	METHOTREXATE 2.5 MG TABLET
NDC	54569181802	METHOTREXATE 2.5 MG TABLET
NDC	54868382608	METHOTREXATE 2.5 MG TABLET
NDC	54868382609	METHOTREXATE 2.5 MG TABLET
NDC	58469399830	METHOTREXATE 2.5 MG TABLET
NDC	59651018201	METHOTREXATE 2.5 MG TABLET
NDC	60429008036	METHOTREXATE 2.5 MG TABLET
NDC	63629147201	METHOTREXATE 2.5 MG TABLET
NDC	63629147202	METHOTREXATE 2.5 MG TABLET
NDC	68382077501	METHOTREXATE 2.5 MG TABLET
NDC	69238142301	METHOTREXATE 2.5 MG TABLET
NDC	69238142306	METHOTREXATE 2.5 MG TABLET
NDC	00719154410	METHOTREXATE 2.5 MG TABLET
NDC	00904601260	METHOTREXATE 2.5 MG TABLET
NDC	00904714110	METHOTREXATE 2.5 MG TABLET
NDC	00054855003	METHOTREXATE 2.5MG TAB DS PK
NDC	00054855005	METHOTREXATE 2.5MG TAB DS PK
NDC	00054855006	METHOTREXATE 2.5MG TAB DS PK
NDC	00054855007	METHOTREXATE 2.5MG TAB DS PK
NDC	00054855010	METHOTREXATE 2.5MG TAB DS PK
NDC	54868382600	METHOTREXATE 2.5MG TAB DS PK
NDC	54868382601	METHOTREXATE 2.5MG TAB DS PK

Code Type	Code	Description
NDC	54868382602	METHOTREXATE 2.5MG TAB DS PK
NDC	00555057245	METHOTREXATE 2.5MG TAB DS PK
NDC	00555057246	METHOTREXATE 2.5MG TAB DS PK
NDC	00555057247	METHOTREXATE 2.5MG TAB DS PK
NDC	00555057248	METHOTREXATE 2.5MG TAB DS PK
NDC	00555057249	METHOTREXATE 2.5MG TAB DS PK
NDC	11845110401	METHOTREXATE 2.5MG TABLET
NDC	00182153901	METHOTREXATE 2.5MG TABLET
NDC	00182153995	METHOTREXATE 2.5MG TABLET
NDC	21695011100	METHOTREXATE 2.5MG TABLET
NDC	23490588900	METHOTREXATE 2.5MG TABLET
NDC	00364249901	METHOTREXATE 2.5MG TABLET
NDC	00364249936	METHOTREXATE 2.5MG TABLET
NDC	00378001401	METHOTREXATE 2.5MG TABLET
NDC	00378001450	METHOTREXATE 2.5MG TABLET
NDC	00405464301	METHOTREXATE 2.5MG TABLET
NDC	00405464336	METHOTREXATE 2.5MG TABLET
NDC	49999038024	METHOTREXATE 2.5MG TABLET
NDC	51079067001	METHOTREXATE 2.5MG TABLET
NDC	51079067005	METHOTREXATE 2.5MG TABLET
NDC	51079067086	METHOTREXATE 2.5MG TABLET
NDC	51079067087	METHOTREXATE 2.5MG TABLET
NDC	51079067088	METHOTREXATE 2.5MG TABLET
NDC	51079067089	METHOTREXATE 2.5MG TABLET
NDC	51285050902	METHOTREXATE 2.5MG TABLET
NDC	52959024400	METHOTREXATE 2.5MG TABLET
NDC	53002048720	METHOTREXATE 2.5MG TABLET
NDC	00536399801	METHOTREXATE 2.5MG TABLET
NDC	00536399836	METHOTREXATE 2.5MG TABLET
NDC	00054455015	METHOTREXATE 2.5MG TABLET
NDC	00054455025	METHOTREXATE 2.5MG TABLET
NDC	00005450723	METHOTREXATE 2.5MG TABLET
NDC	54569181800	METHOTREXATE 2.5MG TABLET
NDC	54569181803	METHOTREXATE 2.5MG TABLET
NDC	54569181809	METHOTREXATE 2.5MG TABLET
NDC	00054855025	METHOTREXATE 2.5MG TABLET
NDC	54868382603	METHOTREXATE 2.5MG TABLET
NDC	54868382604	METHOTREXATE 2.5MG TABLET

Code Type	Code	Description
NDC	54868382605	METHOTREXATE 2.5MG TABLET
NDC	54868382606	METHOTREXATE 2.5MG TABLET
NDC	54868382607	METHOTREXATE 2.5MG TABLET
NDC	55289092430	METHOTREXATE 2.5MG TABLET
NDC	00555057202	METHOTREXATE 2.5MG TABLET
NDC	00555057235	METHOTREXATE 2.5MG TABLET
NDC	59911587401	METHOTREXATE 2.5MG TABLET
NDC	00603449921	METHOTREXATE 2.5MG TABLET
NDC	62584078201	METHOTREXATE 2.5MG TABLET
NDC	62701094036	METHOTREXATE 2.5MG TABLET
NDC	62701094099	METHOTREXATE 2.5MG TABLET
NDC	67253032010	METHOTREXATE 2.5MG TABLET
NDC	67253032036	METHOTREXATE 2.5MG TABLET
NDC	00677161001	METHOTREXATE 2.5MG TABLET
NDC	68115063200	METHOTREXATE 2.5MG TABLET
NDC	00781107601	METHOTREXATE 2.5MG TABLET
NDC	00781107636	METHOTREXATE 2.5MG TABLET
NDC	00839790506	METHOTREXATE 2.5MG TABLET
NDC	00904174960	METHOTREXATE 2.5MG TABLET
NDC	00904174973	METHOTREXATE 2.5MG TABLET
NDC	66479013721	METHOTREXATE 20MG VIAL
NDC	00469197010	METHOTREXATE 25 MG/ML VIAL
NDC	00469197020	METHOTREXATE 25 MG/ML VIAL
NDC	00469197030	METHOTREXATE 25 MG/ML VIAL
NDC	00469216010	METHOTREXATE 25 MG/ML VIAL
NDC	61703035009	METHOTREXATE 25 MG/ML VIAL
NDC	61703035010	METHOTREXATE 25 MG/ML VIAL
NDC	61703035037	METHOTREXATE 25 MG/ML VIAL
NDC	66758004001	METHOTREXATE 25 MG/ML VIAL
NDC	67457022102	METHOTREXATE 25 MG/ML VIAL
NDC	67457022110	METHOTREXATE 25 MG/ML VIAL
NDC	67457022140	METHOTREXATE 25 MG/ML VIAL
NDC	00703367101	METHOTREXATE 25 MG/ML VIAL
NDC	00703367103	METHOTREXATE 25 MG/ML VIAL
NDC	00703367191	METHOTREXATE 25 MG/ML VIAL
NDC	00703367193	METHOTREXATE 25 MG/ML VIAL
NDC	00703367301	METHOTREXATE 25 MG/ML VIAL
NDC	00703367501	METHOTREXATE 25 MG/ML VIAL

Code Type	Code	Description
NDC	00703367591	METHOTREXATE 25 MG/ML VIAL
NDC	00703367801	METHOTREXATE 25 MG/ML VIAL
NDC	54868479600	METHOTREXATE 25MG/ML VIAL
NDC	61703035038	METHOTREXATE 25MG/ML VIAL
NDC	61703040822	METHOTREXATE 25MG/ML VIAL
NDC	61703040841	METHOTREXATE 25MG/ML VIAL
NDC	66479013501	METHOTREXATE 25MG/ML VIAL
NDC	66479013509	METHOTREXATE 25MG/ML VIAL
NDC	66758004002	METHOTREXATE 25MG/ML VIAL
NDC	66758004008	METHOTREXATE 25MG/ML VIAL
NDC	66758004101	METHOTREXATE 25MG/ML VIAL
NDC	00205532719	METHOTREXATE LPF 25 MG/ML VIAL
NDC	00205532526	METHOTREXATE LPF 25MG/ML VIAL
NDC	00205532618	METHOTREXATE LPF 25MG/ML VIAL
NDC	00205532730	METHOTREXATE LPF 25MG/ML VIAL
NDC	00205533734	METHOTREXATE LPF 25MG/ML VIAL
NDC	00205533798	METHOTREXATE LPF 25MG/ML VIAL
NDC	54569452500	METHOTREXATE LPF 25MG/ML VIAL
NDC	58406068312	METHOTREXATE LPF 25MG/ML VIAL
NDC	58406068315	METHOTREXATE LPF 25MG/ML VIAL
NDC	58406068316	METHOTREXATE LPF 25MG/ML VIAL
NDC	58406068318	METHOTREXATE LPF 25MG/ML VIAL
NDC	66479013611	METHOTREXATE LPF 25MG/ML VIAL
NDC	66479013613	METHOTREXATE LPF 25MG/ML VIAL
NDC	66479013619	METHOTREXATE LPF 25MG/ML VIAL
NDC	38779003503	METHOTREXATE POWDER
NDC	38779003504	METHOTREXATE POWDER
NDC	38779003506	METHOTREXATE POWDER
NDC	38779003510	METHOTREXATE POWDER
NDC	38779003511	METHOTREXATE POWDER
NDC	38779003515	METHOTREXATE POWDER
NDC	38779003525	METHOTREXATE POWDER
NDC	49452460001	METHOTREXATE POWDER
NDC	49452460002	METHOTREXATE POWDER
NDC	49452460003	METHOTREXATE POWDER
NDC	51552105401	METHOTREXATE POWDER
NDC	51552105409	METHOTREXATE POWDER
NDC	51927156500	METHOTREXATE POWDER

Code Type	Code	Description
NDC	62991120001	METHOTREXATE POWDER
NDC	62991120002	METHOTREXATE POWDER
NDC	63370015410	METHOTREXATE POWDER
NDC	63370015415	METHOTREXATE POWDER
NDC	63370015425	METHOTREXATE POWDER
NDC	53258152004	METHOTREXATE SODIUM 100 MG VIAL
NDC	66479013929	METHOTREXATE SODIUM 1G VIAL
NDC	00418014820	METHOTREXATE SODIUM 20 MG VIAL
NDC	00469148040	METHOTREXATE SODIUM 20 MG VIAL
NDC	51309020830	METHOTREXATE SODIUM 20 MG VIAL
NDC	53258148004	METHOTREXATE SODIUM 20 MG VIAL
NDC	54569155000	METHOTREXATE SODIUM 20 MG VIAL
NDC	54569184601	METHOTREXATE SODIUM 20 MG VIAL
NDC	00143951901	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00143951910	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	16729027703	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	16729027730	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	16729027735	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00186142013	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00186142113	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00186142212	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00186142304	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00418019702	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00418019704	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00418019708	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00418021602	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00469288030	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020605	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020610	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020615	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020705	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020710	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020715	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	51309020720	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	53258197001	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	53258197002	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	53258197003	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	53258288003	METHOTREXATE SODIUM 25 MG/ML VIAL

Code Type	Code	Description
NDC	53258288030	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	53443058232	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	54569140700	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	61703040825	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457046610	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457046721	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457046799	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457048040	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457048508	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457048599	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457048604	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	67457048699	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014601	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014602	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014701	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014702	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014801	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069014901	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069018101	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069018102	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069020401	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00069020410	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00703367881	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00094532553	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00094532561	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	00094532569	METHOTREXATE SODIUM 25 MG/ML VIAL
NDC	10019094001	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	10019094002	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	10019094101	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	10139006202	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	10139006210	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	10139006240	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	53905003110	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	53905003210	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	53905003310	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	53905003410	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	54569531600	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	54868017301	METHOTREXATE SODIUM 25MG/ML VIAL

Code Type	Code	Description
NDC	54868471600	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	55390003110	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	55390003210	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	55390003310	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	55390003410	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040707	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040732	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040804	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040807	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040813	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040832	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	61703040858	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012102	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012104	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012108	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012110	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012140	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012302	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	63323012310	METHOTREXATE SODIUM 25MG/ML VIAL
NDC	53258149004	METHOTREXATE SODIUM 50 MG VIAL
NDC	00205465302	METHOTREXATE SODIUM PARENTERAL 1G VIAL
NDC	58406067105	METHOTREXATE SODIUM PARENTERAL 1G VIAL
NDC	00005465490	METHOTREXATE SODIUM PARENTERAL 20 MG VIAL
NDC	00205465490	METHOTREXATE SODIUM PARENTERAL 20MG VIAL
NDC	58406067101	METHOTREXATE SODIUM PARENTERAL 20MG VIAL
NDC	58406067301	METHOTREXATE SODIUM PARENTERAL 20MG VIAL
NDC	00205455626	METHOTREXATE SODIUM PARENTERAL 25MG/ML VIAL
NDC	00205533834	METHOTREXATE SODIUM PARENTERAL 25MG/ML VIAL
NDC	58406068114	METHOTREXATE SODIUM PARENTERAL 25MG/ML VIAL
NDC	58406068117	METHOTREXATE SODIUM PARENTERAL 25MG/ML VIAL
NDC	00205933792	METHOTREXATE SODIUM PARENTERAL 50MG VIAL
NDC	58406067103	METHOTREXATE SODIUM PARENTERAL 50MG VIAL
NDC	00015305020	MEXATE 20 MG VIAL
NDC	00015305097	MEXATE 20 MG VIAL
NDC	00015300620	MEXATE-AQ 25 MG/ML VIAL
NDC	00015300697	MEXATE-AQ 25 MG/ML VIAL
NDC	00015300720	MEXATE-AQ 25 MG/ML VIAL
NDC	00015300797	MEXATE-AQ 25 MG/ML VIAL

Code Type	Code	Description
NDC	00015300820	MEXATE-AQ 25 MG/ML VIAL
NDC	00015300897	MEXATE-AQ 25 MG/ML VIAL
NDC	54436001002	OTREXUP 10MG/0.4ML AUTO INJCT
NDC	54436001004	OTREXUP 10MG/0.4ML AUTO INJCT
NDC	54436001202	OTREXUP 12.5MG/0.4 AUTO INJCT
NDC	54436001204	OTREXUP 12.5MG/0.4 AUTO INJCT
NDC	54436001502	OTREXUP 15MG/0.4ML AUTO INJCT
NDC	54436001504	OTREXUP 15MG/0.4ML AUTO INJCT
NDC	54436001702	OTREXUP 17.5MG/0.4 AUTO INJCT
NDC	54436001704	OTREXUP 17.5MG/0.4 AUTO INJCT
NDC	54436002002	OTREXUP 20MG/0.4ML AUTO INJCT
NDC	54436002004	OTREXUP 20MG/0.4ML AUTO INJCT
NDC	54436002202	OTREXUP 22.5MG/0.4 AUTO INJCT
NDC	54436002204	OTREXUP 22.5MG/0.4 AUTO INJCT
NDC	54436002502	OTREXUP 25MG/0.4ML AUTO INJCT
NDC	54436002504	OTREXUP 25MG/0.4ML AUTO INJCT
NDC	54436007502	OTREXUP 7.5 MG/0.4 AUTO INJCT
NDC	54436007504	OTREXUP 7.5 MG/0.4 AUTO INJCT
NDC	00024156104	PLAQUENIL 200 MG TABLET
NDC	24987056210	PLAQUENIL 200 MG TABLET
NDC	42291033590	PLAQUENIL 200 MG TABLET
NDC	43353099709	PLAQUENIL 200 MG TABLET
NDC	43353099753	PLAQUENIL 200 MG TABLET
NDC	43353099760	PLAQUENIL 200 MG TABLET
NDC	54569146801	PLAQUENIL 200 MG TABLET
NDC	59212056210	PLAQUENIL 200 MG TABLET
NDC	59212056211	PLAQUENIL 200 MG TABLET
NDC	71205044812	PLAQUENIL 200 MG TABLET
NDC	71610047330	PLAQUENIL 200 MG TABLET
NDC	71610047353	PLAQUENIL 200 MG TABLET
NDC	71610047380	PLAQUENIL 200 MG TABLET
NDC	00024156210	PLAQUENIL 200MG TABLET
NDC	53002048560	PLAQUENIL 200MG TABLET
NDC	54569146800	PLAQUENIL 200MG TABLET
NDC	54569861600	PLAQUENIL 200MG TABLET
NDC	29936037701	QUINEPROX 200MG TABLET
NDC	52761037701	QUINEPROX 200MG TABLET
NDC	59137051000	RASUVO 10MG/0.2ML AUTO INJCT

Code Type	Code	Description
NDC	59137051004	RASUVO 10MG/0.2ML AUTO INJCT
NDC	59137051500	RASUVO 12.5/0.25 AUTO INJCT
NDC	59137051504	RASUVO 12.5/0.25 AUTO INJCT
NDC	59137052000	RASUVO 15MG/0.3ML AUTO INJCT
NDC	59137052004	RASUVO 15MG/0.3ML AUTO INJCT
NDC	59137052500	RASUVO 17.5/0.35 AUTO INJCT
NDC	59137052504	RASUVO 17.5/0.35 AUTO INJCT
NDC	59137053000	RASUVO 20MG/0.4ML AUTO INJCT
NDC	59137053001	RASUVO 20MG/0.4ML AUTO INJCT
NDC	59137053004	RASUVO 20MG/0.4ML AUTO INJCT
NDC	59137053500	RASUVO 22.5/0.45 AUTO INJCT
NDC	59137053504	RASUVO 22.5/0.45 AUTO INJCT
NDC	59137054000	RASUVO 25MG/0.5ML AUTO INJCT
NDC	59137054004	RASUVO 25MG/0.5ML AUTO INJCT
NDC	59137054500	RASUVO 27.5/0.55 AUTO INJCT
NDC	59137054504	RASUVO 27.5/0.55 AUTO INJCT
NDC	59137055000	RASUVO 30MG/0.6ML AUTO INJCT
NDC	59137055004	RASUVO 30MG/0.6ML AUTO INJCT
NDC	59137050500	RASUVO 7.5MG/0.15 AUTO INJCT
NDC	59137050504	RASUVO 7.5MG/0.15 AUTO INJCT
NDC	66220081011	REDITREX 10MG/0.4ML SYRINGE
NDC	66220081022	REDITREX 10MG/0.4ML SYRINGE
NDC	66220081211	REDITREX 12.5MG/0.5 SYRINGE
NDC	66220081222	REDITREX 12.5MG/0.5 SYRINGE
NDC	66220081511	REDITREX 15MG/0.6ML SYRINGE
NDC	66220081522	REDITREX 15MG/0.6ML SYRINGE
NDC	66220081711	REDITREX 17.5MG/0.7 SYRINGE
NDC	66220081722	REDITREX 17.5MG/0.7 SYRINGE
NDC	66220082011	REDITREX 20MG/0.8ML SYRINGE
NDC	66220082022	REDITREX 20MG/0.8ML SYRINGE
NDC	66220082211	REDITREX 22.5MG/0.9 SYRINGE
NDC	66220082222	REDITREX 22.5MG/0.9 SYRINGE
NDC	66220082511	REDITREX 25 MG/ML SYRINGE
NDC	66220082522	REDITREX 25 MG/ML SYRINGE
NDC	66220080711	REDITREX 7.5MG/.3ML SYRINGE
NDC	66220080722	REDITREX 7.5MG/.3ML SYRINGE
NDC	00005450704	RHEUMATREX 2.5MG TAB DS PK
NDC	00005450705	RHEUMATREX 2.5MG TAB DS PK

Code Type	Code	Description
NDC	00005450707	RHEUMATREX 2.5MG TAB DS PK
NDC	00005450709	RHEUMATREX 2.5MG TAB DS PK
NDC	00005450791	RHEUMATREX 2.5MG TAB DS PK
NDC	67253058042	RHEUMATREX 2.5MG TAB DS PK
NDC	67253058043	RHEUMATREX 2.5MG TAB DS PK
NDC	67253058044	RHEUMATREX 2.5MG TAB DS PK
NDC	67253058045	RHEUMATREX 2.5MG TAB DS PK
NDC	67253058046	RHEUMATREX 2.5MG TAB DS PK
NDC	00032206001	S.A.S.-500 500 MG TABLET
NDC	00032206010	S.A.S.-500 500 MG TABLET
NDC	00032206011	S.A.S.-500 500 MG TABLET
NDC	00032208001	S.A.S.-500 500 MG TABLET
NDC	00032208010	S.A.S.-500 500 MG TABLET
NDC	46198023101	SULFA DYNE 500 MG TABLET
NDC	46198023105	SULFA DYNE 500 MG TABLET
NDC	00102275501	SULFASALAZINE 500 MG TABLET
NDC	10876046105	SULFASALAZINE 500 MG TABLET
NDC	11289211905	SULFASALAZINE 500 MG TABLET
NDC	11845012101	SULFASALAZINE 500 MG TABLET
NDC	11845012103	SULFASALAZINE 500 MG TABLET
NDC	12071034101	SULFASALAZINE 500 MG TABLET
NDC	12071034105	SULFASALAZINE 500 MG TABLET
NDC	00150115240	SULFASALAZINE 500 MG TABLET
NDC	00150115260	SULFASALAZINE 500 MG TABLET
NDC	00150115280	SULFASALAZINE 500 MG TABLET
NDC	00157069601	SULFASALAZINE 500 MG TABLET
NDC	00157069605	SULFASALAZINE 500 MG TABLET
NDC	17022838002	SULFASALAZINE 500 MG TABLET
NDC	17022838004	SULFASALAZINE 500 MG TABLET
NDC	17236028501	SULFASALAZINE 500 MG TABLET
NDC	17236028505	SULFASALAZINE 500 MG TABLET
NDC	17236028510	SULFASALAZINE 500 MG TABLET
NDC	00182101610	SULFASALAZINE 500 MG TABLET
NDC	00228239910	SULFASALAZINE 500 MG TABLET
NDC	00228239950	SULFASALAZINE 500 MG TABLET
NDC	23155001901	SULFASALAZINE 500 MG TABLET
NDC	00302671001	SULFASALAZINE 500 MG TABLET
NDC	00302671005	SULFASALAZINE 500 MG TABLET

Code Type	Code	Description
NDC	00304026900	SULFASALAZINE 500 MG TABLET
NDC	00304026901	SULFASALAZINE 500 MG TABLET
NDC	00304026905	SULFASALAZINE 500 MG TABLET
NDC	00306647090	SULFASALAZINE 500 MG TABLET
NDC	00349234900	SULFASALAZINE 500 MG TABLET
NDC	00349234901	SULFASALAZINE 500 MG TABLET
NDC	00349234905	SULFASALAZINE 500 MG TABLET
NDC	00349234998	SULFASALAZINE 500 MG TABLET
NDC	35470005901	SULFASALAZINE 500 MG TABLET
NDC	35470005905	SULFASALAZINE 500 MG TABLET
NDC	35470008705	SULFASALAZINE 500 MG TABLET
NDC	00359037010	SULFASALAZINE 500 MG TABLET
NDC	00359037040	SULFASALAZINE 500 MG TABLET
NDC	00359037050	SULFASALAZINE 500 MG TABLET
NDC	00364044401	SULFASALAZINE 500 MG TABLET
NDC	00364044405	SULFASALAZINE 500 MG TABLET
NDC	00368102001	SULFASALAZINE 500 MG TABLET
NDC	38022032801	SULFASALAZINE 500 MG TABLET
NDC	45124007801	SULFASALAZINE 500 MG TABLET
NDC	45124007805	SULFASALAZINE 500 MG TABLET
NDC	45124007810	SULFASALAZINE 500 MG TABLET
NDC	47202237101	SULFASALAZINE 500 MG TABLET
NDC	47202237102	SULFASALAZINE 500 MG TABLET
NDC	49648026900	SULFASALAZINE 500 MG TABLET
NDC	49648026901	SULFASALAZINE 500 MG TABLET
NDC	49648026905	SULFASALAZINE 500 MG TABLET
NDC	50268073011	SULFASALAZINE 500 MG TABLET
NDC	50268073015	SULFASALAZINE 500 MG TABLET
NDC	50430004003	SULFASALAZINE 500 MG TABLET
NDC	50430004005	SULFASALAZINE 500 MG TABLET
NDC	50430004006	SULFASALAZINE 500 MG TABLET
NDC	51079004420	SULFASALAZINE 500 MG TABLET
NDC	51079004440	SULFASALAZINE 500 MG TABLET
NDC	51079004450	SULFASALAZINE 500 MG TABLET
NDC	51432044200	SULFASALAZINE 500 MG TABLET
NDC	51432044203	SULFASALAZINE 500 MG TABLET
NDC	51432044205	SULFASALAZINE 500 MG TABLET
NDC	51728004601	SULFASALAZINE 500 MG TABLET

Code Type	Code	Description
NDC	51728004605	SULFASALAZINE 500 MG TABLET
NDC	52446044421	SULFASALAZINE 500 MG TABLET
NDC	52446044428	SULFASALAZINE 500 MG TABLET
NDC	52728028510	SULFASALAZINE 500 MG TABLET
NDC	53258017213	SULFASALAZINE 500 MG TABLET
NDC	00537614801	SULFASALAZINE 500 MG TABLET
NDC	00537614810	SULFASALAZINE 500 MG TABLET
NDC	54274000410	SULFASALAZINE 500 MG TABLET
NDC	54274000430	SULFASALAZINE 500 MG TABLET
NDC	54569007227	SULFASALAZINE 500 MG TABLET
NDC	54569007250	SULFASALAZINE 500 MG TABLET
NDC	54569031300	SULFASALAZINE 500 MG TABLET
NDC	54569031302	SULFASALAZINE 500 MG TABLET
NDC	55081050100	SULFASALAZINE 500 MG TABLET
NDC	55081050101	SULFASALAZINE 500 MG TABLET
NDC	00580033101	SULFASALAZINE 500 MG TABLET
NDC	00580033105	SULFASALAZINE 500 MG TABLET
NDC	00591550301	SULFASALAZINE 500 MG TABLET
NDC	00591550303	SULFASALAZINE 500 MG TABLET
NDC	00591550304	SULFASALAZINE 500 MG TABLET
NDC	59762500005	SULFASALAZINE 500 MG TABLET
NDC	59762500006	SULFASALAZINE 500 MG TABLET
NDC	00615152201	SULFASALAZINE 500 MG TABLET
NDC	00615152205	SULFASALAZINE 500 MG TABLET
NDC	62135096001	SULFASALAZINE 500 MG TABLET
NDC	62135096005	SULFASALAZINE 500 MG TABLET
NDC	62135096010	SULFASALAZINE 500 MG TABLET
NDC	62135096031	SULFASALAZINE 500 MG TABLET
NDC	71610057770	SULFASALAZINE 500 MG TABLET
NDC	71610057780	SULFASALAZINE 500 MG TABLET
NDC	00719192810	SULFASALAZINE 500 MG TABLET
NDC	00719192812	SULFASALAZINE 500 MG TABLET
NDC	00719192813	SULFASALAZINE 500 MG TABLET
NDC	00725005901	SULFASALAZINE 500 MG TABLET
NDC	00725005904	SULFASALAZINE 500 MG TABLET
NDC	00725005905	SULFASALAZINE 500 MG TABLET
NDC	00725005910	SULFASALAZINE 500 MG TABLET
NDC	00779102525	SULFASALAZINE 500 MG TABLET

Code Type	Code	Description
NDC	00779105225	SULFASALAZINE 500 MG TABLET
NDC	00779105227	SULFASALAZINE 500 MG TABLET
NDC	00781104501	SULFASALAZINE 500 MG TABLET
NDC	00781104505	SULFASALAZINE 500 MG TABLET
NDC	00814723014	SULFASALAZINE 500 MG TABLET
NDC	00839609816	SULFASALAZINE 500 MG TABLET
NDC	00904115261	SULFASALAZINE 500 MG TABLET
NDC	00904115270	SULFASALAZINE 500 MG TABLET
NDC	00904115280	SULFASALAZINE 500 MG TABLET
NDC	00948520201	SULFASALAZINE 500 MG TABLET
NDC	17236029101	SULFASALAZINE 500 MG TABLET DR
NDC	17236029105	SULFASALAZINE 500 MG TABLET DR
NDC	00302671201	SULFASALAZINE 500 MG TABLET DR
NDC	00302671205	SULFASALAZINE 500 MG TABLET DR
NDC	00304117901	SULFASALAZINE 500 MG TABLET DR
NDC	00306646185	SULFASALAZINE 500 MG TABLET DR
NDC	00349829201	SULFASALAZINE 500 MG TABLET DR
NDC	00349829205	SULFASALAZINE 500 MG TABLET DR
NDC	35470024801	SULFASALAZINE 500 MG TABLET DR
NDC	00359036710	SULFASALAZINE 500 MG TABLET DR
NDC	00364068801	SULFASALAZINE 500 MG TABLET DR
NDC	47202271001	SULFASALAZINE 500 MG TABLET DR
NDC	49648117901	SULFASALAZINE 500 MG TABLET DR
NDC	51079015540	SULFASALAZINE 500 MG TABLET DR
NDC	51079015550	SULFASALAZINE 500 MG TABLET DR
NDC	51432044103	SULFASALAZINE 500 MG TABLET DR
NDC	51432044105	SULFASALAZINE 500 MG TABLET DR
NDC	51728064801	SULFASALAZINE 500 MG TABLET DR
NDC	51728064805	SULFASALAZINE 500 MG TABLET DR
NDC	52446044621	SULFASALAZINE 500 MG TABLET DR
NDC	00536461301	SULFASALAZINE 500 MG TABLET DR
NDC	00536461305	SULFASALAZINE 500 MG TABLET DR
NDC	54274005210	SULFASALAZINE 500 MG TABLET DR
NDC	54274005230	SULFASALAZINE 500 MG TABLET DR
NDC	57362046184	SULFASALAZINE 500 MG TABLET DR
NDC	00580146001	SULFASALAZINE 500 MG TABLET DR
NDC	00580146005	SULFASALAZINE 500 MG TABLET DR
NDC	00719192710	SULFASALAZINE 500 MG TABLET DR

Code Type	Code	Description
NDC	00725013101	SULFASALAZINE 500 MG TABLET DR
NDC	00725013105	SULFASALAZINE 500 MG TABLET DR
NDC	00725013110	SULFASALAZINE 500 MG TABLET DR
NDC	00779013101	SULFASALAZINE 500 MG TABLET DR
NDC	00814723114	SULFASALAZINE 500 MG TABLET DR
NDC	00814723128	SULFASALAZINE 500 MG TABLET DR
NDC	00839674406	SULFASALAZINE 500 MG TABLET DR
NDC	00839674412	SULFASALAZINE 500 MG TABLET DR
NDC	00904115140	SULFASALAZINE 500 MG TABLET DR
NDC	00904115160	SULFASALAZINE 500 MG TABLET DR
NDC	00904115180	SULFASALAZINE 500 MG TABLET DR
NDC	00948515901	SULFASALAZINE 500 MG TABLET DR
NDC	00182101601	SULFASALAZINE 500MG TABLET
NDC	00182101605	SULFASALAZINE 500MG TABLET
NDC	00223172701	SULFASALAZINE 500MG TABLET
NDC	00223172702	SULFASALAZINE 500MG TABLET
NDC	00223172705	SULFASALAZINE 500MG TABLET
NDC	23490631300	SULFASALAZINE 500MG TABLET
NDC	00405495601	SULFASALAZINE 500MG TABLET
NDC	00405495602	SULFASALAZINE 500MG TABLET
NDC	43353049553	SULFASALAZINE 500MG TABLET
NDC	43353049570	SULFASALAZINE 500MG TABLET
NDC	43353049580	SULFASALAZINE 500MG TABLET
NDC	00440842091	SULFASALAZINE 500MG TABLET
NDC	49727004204	SULFASALAZINE 500MG TABLET
NDC	49999098100	SULFASALAZINE 500MG TABLET
NDC	51382010701	SULFASALAZINE 500MG TABLET
NDC	51382010705	SULFASALAZINE 500MG TABLET
NDC	52544079601	SULFASALAZINE 500MG TABLET
NDC	52544079605	SULFASALAZINE 500MG TABLET
NDC	52544079610	SULFASALAZINE 500MG TABLET
NDC	53002029700	SULFASALAZINE 500MG TABLET
NDC	53489014701	SULFASALAZINE 500MG TABLET
NDC	53489014705	SULFASALAZINE 500MG TABLET
NDC	53489014710	SULFASALAZINE 500MG TABLET
NDC	00536461701	SULFASALAZINE 500MG TABLET
NDC	00536461705	SULFASALAZINE 500MG TABLET
NDC	00536461710	SULFASALAZINE 500MG TABLET

Code Type	Code	Description
NDC	00005396031	SULFASALAZINE 500MG TABLET
NDC	54569031301	SULFASALAZINE 500MG TABLET
NDC	54569031303	SULFASALAZINE 500MG TABLET
NDC	54868113800	SULFASALAZINE 500MG TABLET
NDC	54868113801	SULFASALAZINE 500MG TABLET
NDC	54868113803	SULFASALAZINE 500MG TABLET
NDC	54868113804	SULFASALAZINE 500MG TABLET
NDC	54868113805	SULFASALAZINE 500MG TABLET
NDC	54868113806	SULFASALAZINE 500MG TABLET
NDC	55289017610	SULFASALAZINE 500MG TABLET
NDC	55289017640	SULFASALAZINE 500MG TABLET
NDC	56126030611	SULFASALAZINE 500MG TABLET
NDC	58016007400	SULFASALAZINE 500MG TABLET
NDC	58016007430	SULFASALAZINE 500MG TABLET
NDC	58016007460	SULFASALAZINE 500MG TABLET
NDC	58016007490	SULFASALAZINE 500MG TABLET
NDC	00591079601	SULFASALAZINE 500MG TABLET
NDC	00591079605	SULFASALAZINE 500MG TABLET
NDC	00591079610	SULFASALAZINE 500MG TABLET
NDC	59762500001	SULFASALAZINE 500MG TABLET
NDC	59762500002	SULFASALAZINE 500MG TABLET
NDC	60346081240	SULFASALAZINE 500MG TABLET
NDC	60346081294	SULFASALAZINE 500MG TABLET
NDC	00603580221	SULFASALAZINE 500MG TABLET
NDC	00603580228	SULFASALAZINE 500MG TABLET
NDC	61392014730	SULFASALAZINE 500MG TABLET
NDC	61392014731	SULFASALAZINE 500MG TABLET
NDC	61392014732	SULFASALAZINE 500MG TABLET
NDC	61392014739	SULFASALAZINE 500MG TABLET
NDC	61392014745	SULFASALAZINE 500MG TABLET
NDC	61392014751	SULFASALAZINE 500MG TABLET
NDC	61392014754	SULFASALAZINE 500MG TABLET
NDC	61392014760	SULFASALAZINE 500MG TABLET
NDC	61392014790	SULFASALAZINE 500MG TABLET
NDC	61392014791	SULFASALAZINE 500MG TABLET
NDC	00615152253	SULFASALAZINE 500MG TABLET
NDC	00615152263	SULFASALAZINE 500MG TABLET
NDC	00615152265	SULFASALAZINE 500MG TABLET

Code Type	Code	Description
NDC	00659010605	SULFASALAZINE 500MG TABLET
NDC	00677048301	SULFASALAZINE 500MG TABLET
NDC	00677048305	SULFASALAZINE 500MG TABLET
NDC	68258908601	SULFASALAZINE 500MG TABLET
NDC	00814723028	SULFASALAZINE 500MG TABLET
NDC	00839609806	SULFASALAZINE 500MG TABLET
NDC	00839609812	SULFASALAZINE 500MG TABLET
NDC	00904115240	SULFASALAZINE 500MG TABLET
NDC	00904115260	SULFASALAZINE 500MG TABLET
NDC	00254590528	SULFASALAZINE 500MG TABLET DR
NDC	59762010401	SULFASALAZINE 500MG TABLET DR
NDC	59762010402	SULFASALAZINE 500MG TABLET DR
NDC	59762010405	SULFASALAZINE DR 500 MG TABLET DR
NDC	59762010406	SULFASALAZINE DR 500 MG TABLET DR
NDC	54868113900	SULFASALAZINE EC 500MG TABLET DR
NDC	38779017604	SULFASALAZINE POWDER
NDC	38779017605	SULFASALAZINE POWDER
NDC	38779017608	SULFASALAZINE POWDER
NDC	38779017609	SULFASALAZINE POWDER
NDC	38779017610	SULFASALAZINE POWDER
NDC	38779017625	SULFASALAZINE POWDER
NDC	38779017644	SULFASALAZINE POWDER
NDC	49452752301	SULFASALAZINE POWDER
NDC	49452752302	SULFASALAZINE POWDER
NDC	51552104405	SULFASALAZINE POWDER
NDC	51927104500	SULFASALAZINE POWDER
NDC	62991270401	SULFASALAZINE POWDER
NDC	62991270403	SULFASALAZINE POWDER
NDC	62991270404	SULFASALAZINE POWDER
NDC	10544028830	SULFAZINE 500 MG TABLET
NDC	67544094370	SULFAZINE 500 MG TABLET
NDC	67544094380	SULFAZINE 500 MG TABLET
NDC	00603580104	SULFAZINE 500MG TABLET
NDC	00603580121	SULFAZINE 500MG TABLET
NDC	00603580128	SULFAZINE 500MG TABLET
NDC	00603580132	SULFAZINE 500MG TABLET
NDC	00603580321	SULFAZINE EC 500MG TABLET DR
NDC	00603580325	SULFAZINE EC 500MG TABLET DR

Code Type	Code	Description
NDC	51285036801	TREXALL 10MG TABLET
NDC	00555092901	TREXALL 10MG TABLET
NDC	51285036901	TREXALL 15MG TABLET
NDC	00555094501	TREXALL 15MG TABLET
NDC	51285036601	TREXALL 5MG TABLET
NDC	00555092701	TREXALL 5MG TABLET
NDC	51285036701	TREXALL 7.5MG TABLET
NDC	00555092801	TREXALL 7.5MG TABLET
NDC	52652200101	XATMEP 2.5 MG/ML SOLUTION
NDC	52652200106	XATMEP 2.5 MG/ML SOLUTION

Emergency room visit with RA as primary diagnosis

Emergency room visits associated with a diagnosis of RA (ICD-10 codes: M05* and M06*, except M06.1, M06.4) will be identified based on the presence of evaluation and management codes associated with emergency department visits and place of service codes.

Hospitalization with RA as primary diagnosis

Hospitalizations associated with a diagnosis of RA (ICD-10 code: M05* and M06*, except M06.1, M06.4) will be identified based on revenue codes, place of service codes, and provider specialty.

Document Approval Record

Document Name:	A3921427_PROTOCOL- XELJANZ SHINGRIZ PASS_V2.1_05OCT2023
Document Title:	A3921427_PROTOCOL- XELJANZ SHINGRIZ PASS_V2.1_05OCT2023

Signed By:	Date(GMT)	Signing Capacity
De Bernardi, Barbara	31-Oct-2023 15:47:51	EUQPPV Approval
Rubino, Heather	31-Oct-2023 16:43:15	Manager Approval