NON-INTERVENTIONAL (NI) STUDY PROTOCOL

Study information

Title	Post-Approval Observational Cohort Study to Evaluate the Safety of the COMIRNATY 2023-2024 Formula in the United States
Protocol number	C4591062
Protocol version identifier	3.0
Date	18 March 2026
EU Post Authorization Study (PAS) register number	To be determined
Active substance	COVID-19 Vaccine, mRNA
Medicinal product	COMIRNATY 2023-2024 Formula
Country of study	United States
Research question and objectives	Research question: What is the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula in the United States? <u>Phase 1</u> Primary objective: • To estimate the incidence of pre-specified safety events of interest following vaccination with the COMIRNATY 2023-2024 Formula compared to the incidence of these events during a control window (i.e., expected rates of these events). <u>Phase 2</u> Primary objective: • To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula. Secondary objective: • To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula among subgroups of individuals with concomitant administration of a non-COVID-19 vaccine; immunocompromised individuals; individuals with specific comorbidities; individuals with prior SARS-CoV-2 infection;

	individuals with prior COVID-19 vaccination; pregnant women; pediatric subjects; and the elderly, if sample size permits.
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2. LIST OF ABBREVIATIONS

Abbreviation	Definition
ADEM	Acute disseminated encephalomyelitis
AE	Adverse event
AMA	American Medical Association
ASD	Atrial septal defect
AVSD	Atrioventricular septal defect
BEST	Biologics Effectiveness and Safety
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CHD	Congenital heart disease
CMS	Centers for Medicare and Medicaid Services
CI	Confidence interval
CIOMS	Council for International Organizations of Medical Sciences
COPD	Chronic obstructive pulmonary disease
COVID-19	Coronavirus disease 2019
CPT	Current Procedural Terminology
CVST	Cerebral venous sinus thrombosis
EC	Ethics committee
ED	Emergency department
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
FDA	Food and Drug Administration
GPP	Good pharmacoepidemiology practices
HCPCS	Healthcare Common Procedure Coding System
HIV	Human deficiency virus
ICD-10	International Classification of Diseases, 10th Revision
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
IIS	Immunization Information Systems
IRB	Institutional Review Board
IP	Inpatient
LMP	Last menstrual period
MI	Myocardial infarction
mRNA	Messenger RNA
MS	Multiple sclerosis
NDC	National Drug Code
NSTEMI	Non-ST elevation myocardial infarction
ORD	Optum Research Database
OP	Outpatient
PAS	Post Authorization Study
PASS	Post-authorization safety studies
PDA	Patent ductus arteriosus

Abbreviation	Definition
PE	Pulmonary embolism
PS	Propensity score
RSV	Respiratory syncytial virus
SAP	Statistical analysis plan
SCRI	Self-controlled risk interval
SOP	Standard operating procedure
STEMI	ST elevation myocardial infarction
TAPVR	Total anomalous pulmonary venous return
US	United States
VAERS	Vaccine Adverse Event Reporting System
VSD	Ventricular septal defect

3. RESPONSIBLE PARTIES

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4. ABSTRACT

Title: Post-Approval Observational Cohort Study to Evaluate the Safety of the COMIRNATY 2023-2024 Formula in the United States

Version: 3.0

Date: 18 March 2026

Authors: Optum: Laura E. Dodge, ScD, Senior Epidemiologist, Epidemiology; Florence T. Wang, ScD, Vice President, Epidemiology; Pfizer: Jenny Sun, PhD, Associate Director, Epidemiology, Safety Surveillance Research

Rationale and background: In September 2023, the FDA authorized the COMIRNATY 2023-2024 Formula, a monovalent mRNA vaccine targeting the Omicron variant XBB.1.5. More information is needed on whether the safety profile of the COMIRNATY 2023-2024 Formula remains consistent with the safety profile of the original formula in the overall population and in subpopulations of interest.

This non-interventional study is designated as a post-authorization safety study (PASS) and is a condition of authorization to the FDA.

Research question and objectives:

Research question: What is the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula in the United States?

Phase 1

Primary objective:

- To estimate the incidence of pre-specified safety events of interest following vaccination with the COMIRNATY 2023-2024 Formula compared to the incidence of these events during a control window (i.e., expected rates of these events).

Phase 2

Primary objective:

- To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula.

Secondary objective:

- To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula among subgroups of individuals with concomitant administration of a non-COVID-19 vaccine; immunocompromised individuals; individuals with specific comorbidities; individuals

with prior SARS-CoV-2 infection; individuals with prior COVID-19 vaccination; pregnant women; pediatric subjects; and the elderly, if sample size permits.

Study design: This is a non-interventional observational study utilizing an administrative claims database in the US. Phase 1 will utilize a self-controlled risk interval (SCRI) design, and Phase 2 will utilize a matched comparative safety cohort design.

Population: The source population for this study will consist of all individuals with at least one medical or pharmacy claim from 11 September 2023 through 31 March 2024. In Phase 1, individuals age ≥ 6 months will be eligible for inclusion if they receive at least one dose of the COMIRNATY 2023-2024 Formula from the date of product launch through 31 March 2024, have continuous medical and pharmacy insurance coverage in the 365 days prior to their vaccination date, experience a safety outcome of interest during a risk or control period, and do not experience the safety event of interest during the clean period prior to vaccination. In Phase 2, individuals age ≥ 6 months will be eligible for inclusion in the exposed cohort if they receive a dose of the COMIRNATY 2023-2024 Formula and have continuous medical and pharmacy insurance coverage in the 365 days prior to their vaccination. Individuals age ≥ 6 months will be eligible for inclusion in the unexposed cohort if they do not receive a dose of the COMIRNATY 2023-2024 Formula but do have a healthcare encounter and if they have continuous medical and pharmacy insurance coverage in the 365 days prior to their healthcare encounter. Individuals in the unexposed cohort will be matched to those in the exposed cohort if their healthcare encounter is in the same 14-day calendar period as the exposed individual's vaccination date and if they are in the same age group.

Variables:

- *Exposures*: Exposure to the COMIRNATY 2023-2024 Formula will be defined by the presence of National Drug Codes (NDC) on pharmacy claims or Healthcare Common Procedure Coding System (HCPCS) codes on medical claims.
- *Outcomes*: The pre-specified safety outcomes of interest include the following: acute disseminated encephalomyelitis (ADEM), anaphylaxis, Bell's palsy, cerebral venous sinus thrombosis (CVST), convulsions/seizures (non-febrile), encephalomyelitis, glomerulonephritis, Guillain-Barré syndrome, herpes zoster, immune-mediated myositis, immune thrombocytopenia, Kawasaki disease, multi inflammatory syndrome (in children and adults), multiple sclerosis (MS), myocardial infarction (MI), myocarditis/pericarditis, pulmonary embolism (PE), hemorrhagic stroke, ischemic stroke, and transverse myelitis. Study outcomes will be identified through claims indicators using published validated claims-based algorithms with high performance when available.
- *Covariates*: Baseline covariates will include information related to patient demographics, comorbidities, COVID-19 vaccination, healthcare utilization, and medication history. Additional baseline covariates will be identified on an empiric basis by examining the most frequently occurring diagnoses, drugs dispensed, and procedures performed among individuals with and without COMIRNATY 2023-2024 Formula exposure. Demographic

attributes will be determined on the vaccination/cohort entry date, while other factors will be assessed in the one year prior to the vaccination date or cohort entry date.

Data sources: The patients included in this study will be drawn from the Optum pre-adjudicated claims database for the interim report and from the Optum Research Database (ORD) for the final reporting. The pre-adjudicated medical claims, which are supplemented with adjudicated pharmacy claims and health plan enrollment information, encompass hospital and physician claims that are submitted and processed daily from a large US commercial health plan. The individuals included in the pre-adjudicated medical claims database are fully insured by the health plan, which provides reimbursement of medical and pharmacy services regardless of site of care, and individuals are geographically diverse within the US. The ORD is a proprietary research database containing eligibility and adjudicated pharmacy and medical claims data from a large US health plan affiliated with Optum. In 2021, data were available for approximately 12.6 million individuals with medical and pharmacy coverage.

Study size: The sample size achieved will depend on the number of recipients of the COMIRNATY 2023-2024 Formula in the databases. All individuals who meet the study's eligibility criteria during the study period will be included.

Data analysis:

Phase 1: For the SCRI design, the observed incidence rates of the pre-specified safety outcomes of interest will be estimated in the risk window and the control window. Among individuals who experience an outcome of interest, an exact conditional Poisson regression model with the natural logarithm of the person-time as the offset will be used to calculate the rate ratio and corresponding 95% confidence interval (CI) of events occurring during the risk period relative to the control period. The results from the SCRI utilizing the Optum pre-adjudicated claims database will be presented in the interim report, while results utilizing the ORD will be presented in the final report.

Phase 2: In the cohort study, propensity score matched cohorts of COMIRNATY 2023-2024 Formula-vaccinated patients and comparator patients with no recorded dose of the COMIRNATY 2023-2024 Formula will be created. Following the application of outcome-specific exclusions, the incidence rate of each safety outcome will be estimated among the COMIRNATY 2023-2024 Formula-exposed group and its matched comparator group. The rate ratio will be estimated using unconditional Poisson regression that accounts for the matching process and for individuals who are included in both study cohorts. Secondary analyses will be conducted separately for various subsets of the matched comparator group, including comparators who received a non-COMIRNATY 2023-2024 COVID-19 vaccine on cohort entry, who received a non-COVID-19 vaccine on cohort entry, and who did not receive a vaccine on cohort entry by had another type of qualifying outpatient health encounter. Subgroup analyses will be conducted among individuals receiving concomitant non-COVID-19 vaccines; immunocompromised individuals; individuals with specific baseline comorbidities; individuals with prior SARS-CoV-2 infection; individuals with prior COVID-19 vaccination; pregnant women; individuals aged < 18 years; and individuals aged

≥ 65 years. Lastly, a descriptive analysis of the matched cohorts will focus specifically on outcomes related to pregnancy (spontaneous abortion, stillbirth, preterm birth, major congenital malformations and small for gestational age).

Milestones: Planned start of data collection is 15 January 2024. Planned completion date for the interim report is 30 June 2024. The planned end of data collection is 31 August 2025, and the planned completion date for the final report is 30 April 2026.

5. AMENDMENTS AND UPDATES

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
3.0	18 March 2026	Administrative	4	Clarified the secondary and subgroup analyses in the abstract	Clarification between secondary and subgroup analyses
3.0	18 March 2026	Substantial	9.3.2.	Expands the circumstances where medical records may be retrieved to include analyses beyond safety signals in the primary SCRI analysis in the interim report	Provides operational flexibility to obtain medical records in the final report or in analyses besides the primary SCRI analysis if a safety signal is detected or if estimates are approaching the safety signal threshold
3.0	18 March 2026	Administrative	9.3.3.	Specified the form of each variable (categorical, continuous, binary)	Additional clarification on the model specification
3.0	18 March 2026	Administrative	9.3.3.	Clarified that other vaccinations are included in the empirical examination	Vaccinations are captured through NDC or CPT codes
3.0	18 March 2026	Administrative	9.7.2.1.	Specified the logistic regression model that will be used to estimate propensity scores, how calendar time will be included, and noted that scores will be matched to a maximum of 8 decimal places	Additional clarification on the model specification and details of propensity score matching
3.0	18 March 2026	Administrative	9.7.2.2.	Specified that the primary analysis accounts for both the matching ratio and individuals included in both study cohorts	Improved clarity of analytic methods
3.0	18 March 2026	Administrative	9.7.2.3.	Specified that the secondary analyses account for both the matching ratio and	Improved clarity of analytic methods

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
				individuals included in both study cohorts	
3.0	18 March 2026	Administrative	9.7.2.4.	Specified that the subgroup analyses will include propensity score as a covariate in the model and will account for individuals included in both study cohorts	Improved clarity of analytic methods
3.0	18 March 2026	Administrative	9.9.	Added to the limitations the potential for residual confounding due to the use of a 1-year covariate period, not including prior COVID-19 vaccination in the propensity score model, and not accounting for other baseline vaccinations besides seasonal influenza and RSV vaccines.	Additional details to clarify the impact on potential confounding
2.0	29 August 2025	Administrative	4, 9.2	Corrected two typographical errors referring to the incorrect start of study accrual for the cohort analysis (corrected to 11 September 2023)	Typographical error in Version 1
2.0	29 August 2025	Substantial	4, 9.2.4, 9.3.3	Covariates will be assessed in the 1 year prior to cohort entry date as opposed to all available data	The 1-year lookback period is sufficient for capturing baseline covariates
2.0	29 August 2025	Administrative	6	Replaced references to 'EU PAS Register' with 'HMA-EMA Catalogues of RWD Studies'	Change in name of the publication registration catalogue
2.0	29 August 2025	Administrative	8	Changed the information about product approval to past tense	The information regarding the 2023-2024 Formula is no

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
					longer present tense
2.0	29 August 2025	Administrative	9.1.2, 9.2.3, 9.7.2.1	Clarified details regarding propensity score matching in the cohort study analysis	Additional details provided for improved clarity
2.0	29 August 2025	Substantial	9.2.1.2, 9.2.2.1	Clarified that individuals receiving any COVID-19 vaccine (including prior COMIRNATY 2023-2024 Formula) would be excluded from the SCRI and cohort analyses	To ensure a proper washout period, excluding prior COMIRNATY 2023-2024 Formula is needed for individuals who may receive more than 1 dose
2.0	29 August 2025	Administrative	9.2.2.1	Corrected a typographical error referring to the incorrect study phase	Typographical error in Version 1
2.0	29 August 2025	Administrative	9.2.3, 9.2.5.2	Added details on the cohort entry date for the comparator cohort	Additional details provided for improved clarity
2.0	29 August 2025	Administrative	9.2.5.2	Specified that follow-up for the cohort study will end at one year following cohort entry (as mentioned in other sections) and clarified the end of follow-up criterion related to receipt of a subsequent COVID-19 vaccine	Additional details provided for improved clarity
2.0	29 August 2025	Administrative	Table 2	Corrected clean periods and vaccine risk windows for select outcomes	Typographical errors in Version 1
2.0	29 August 2025	Administrative	9.3.3	Clarified that prior COVID-19 vaccination will be descriptive only	Variable not included in the propensity score because doses during the 270 days prior to cohort entry are excluded

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
2.0	29 August 2025	Administrative	9.3.3	Clarified that prior COVID-19 vaccination will be a binary variable for receipt of vaccine vs no receipt and will not be examined by year	Quantifying variable by doses prior to 2023-2024 is not possible now that the baseline period is limited to 1 year
2.0	29 August 2025	Administrative	9.3.3, 15.4.2.2	Clarified that the covariate of corticosteroids is restricted to oral routes	Additional details provided for improved clarity
2.0	29 August 2025	Administrative	9.3.3	Clarified the number of most frequently occurring codes that will be examined	Additional details provided for improved clarity
2.0	29 August 2025	Administrative	9.7.1.1	Clarified that the exact conditional Poisson regression model will be used among individuals who experience an outcome of interest in either the risk window or the control window (but not both)	Additional details provided for improved clarity
2.0	29 August 2025	Administrative	9.7.2.3	Changed a numbered list to a bulleted list	Formatting change
2.0	29 August 2025	Substantial	4, 9.7.2.4	Updated the subgroup analysis for individuals ≤ 18 years of age to state that this will be done among individuals < 18 years of age	Revised to match the more commonly used definition for the pediatric population (<18 years)
2.0	29 August 2025	Administrative	9.7.2.4	Clarified that the prevalence of major congenital malformations will be evaluated among individuals whose pregnancy results in a live birth.	Additional details provided for improved clarity

6. MILESTONES

Milestone	Planned Date
Final study protocol	31 March 2024
Registration in the HMA-EMA Catalogues of RWD	To be determined
Start of data collection [a]	15 January 2024
Interim report [b]	30 June 2024
End of data collection [c, d]	31 August 2025
Final study report [d]	30 April 2026

a For studies with secondary data collection, the start of data collection is defined as the planned date for starting data extraction for the purposes of the interim analysis.
b The milestone date was chosen to inform decision making for the next adapted vaccine before Fall 2024. To meet this milestone, the data extraction for the interim reporting will include data through 15 January 2024.
c For studies with secondary data collection, the end of data collection is defined as the planned date on which the analytical dataset will be first completely available; the analytic dataset is the minimum set of data required to perform the statistical analysis for the final reporting.
d The sponsor may extend the study period. This revision, if needed, will be communicated to the FDA as a protocol amendment. Details on this contingency plan are provided in Section 9.2.

7. RATIONALE AND BACKGROUND

The development of vaccines against SARS-CoV-2 has been critical to ending the Coronavirus disease 2019 (COVID-19) pandemic. In the United States (US), the first to become available were the messenger RNA (mRNA) vaccines BNT162B2 (COMIRNATY) (Pfizer Inc/BioNTech, 2023) and mRNA-1273 (Moderna US, Inc., 2023). Authorized for emergency use by the US Food and Drug Administration (FDA) on 11 December 2020 and 18 December 2020, respectively, these first-generation vaccines contained a piece of the original SARS-CoV-2 virus's mRNA, instructing cells in the body to make the virus's distinctive "spike" protein and triggering an immune response (FDA, 2020a, 2020b; Nabizadeh et al., 2023). Beginning in August 2022, in response to the new circulating Omicron variant of SARS-CoV-2, the vaccines were adapted to add an mRNA component from the Omicron lineages BA.4 and BA.5, in addition to mRNA from the original viral strain, and were thereafter referred to as bivalent vaccines (FDA, 2022b, 2022c, 2022d). In September 2023, the COMIRNATY 2023-2024 Formula was approved for individuals ≥ 12 years of age. The Pfizer-BioNTech COVID-19 Vaccine 2023-2024 Formula was authorized under emergency use in individuals 6 months through 11 years of age. This new formulation contains a monovalent (single) mRNA component corresponding to the Omicron variant XBB.1.5 (FDA, 2023b). The Omicron XBB sublineage accounted for nearly all COVID-19 cases in the US in spring 2023 and remained the most common variant as of 08 July 2023 (CDC, 2020).

Based on data from the original COMIRNATY formula, the US prescribing information for COMIRNATY highlights the following warnings and precautions:

- "Postmarketing data demonstrate increased risks of myocarditis and pericarditis"
- "Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY." (Pfizer Inc/BioNTech, 2023)

Additionally, the following serious adverse events have been observed after immunization with the Pfizer-BioNTech, Moderna, and Janssen vaccines as reported in the Vaccine Adverse Event Reporting System (VAERS): glomerulonephritis, herpes zoster, immune-mediated myositis, and relapsing or progressing MS (*VAERS*, 2023). More information is needed on whether the safety profile of the COMIRNATY 2023-2024 Formula remains consistent with the safety profile of the original formula in the overall population and subpopulations of interest.

Pfizer/BioNTech, sponsor of the first COVID-19 vaccine to be authorized in the US, is conducting a non-interventional PASS to collect information on the safety profile of its most recently authorized strain of the COVID-19 vaccine, the Omicron XBB.1.5 monovalent vaccine (COMIRNATY 2023-2024 Formula; Pfizer Inc/BioNTech, 2023). This combined protocol and statistical analysis plan (SAP) describes a non-interventional observational study using claims data from a large US insurer to evaluate the safety of the COMIRNATY 2023-2024 Formula in the general population as well as in subpopulations of interest. This

non-interventional study is designated as a PASS and is a condition of authorization to the FDA.

8. RESEARCH QUESTION AND OBJECTIVES

The research question of this study is: What is the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula in the United States? To answer this question, the study will be conducted in two phases, each with its own specific objectives.

8.1. Phase 1

Phase 1 will be designed to sequentially monitor the occurrence of pre-specified safety events of interest following vaccination.

8.1.1. Primary Objective:

- To estimate the incidence of pre-specified safety events of interest following vaccination with the COMIRNATY 2023-2024 Formula compared to the incidence of these events during a control window (i.e., expected rates of these events).

8.2. Phase 2

Phase 2 will be designed to assess the risk of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination for the COMIRNATY 2023-2024 Formula for up to 1 year after vaccination.

8.2.1. Primary Objective:

- To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination for the COMIRNATY 2023-2024 Formula.

8.2.2. Secondary Objective:

- To estimate the incidence of pre-specified safety events of interest among individuals who receive the COMIRNATY 2023-2024 Formula compared to individuals with no recorded vaccination with the COMIRNATY 2023-2024 Formula among subgroups of individuals with concomitant administration of a non-COVID-19 vaccine; immunocompromised individuals; individuals with specific comorbidities; individuals with prior SARS-CoV-2 infection; individuals with prior COVID-19 vaccination; pregnant women; pediatric subjects; and the elderly, if sample size permits.

9. RESEARCH METHODS

9.1. Study Design

This non-interventional study will be conducted in two phases. Phase 1 will include a study of self-controlled risk interval (SCRI) design conducted using a pre-adjudicated claims database for the interim report. For the final report, the SCRI study will be repeated using the ORD, an adjudicated claims database. Phase 2 will be a comparative safety cohort design using the ORD and will also be included in the final report.

Table 1 summarizes the study designs and data sources included in the interim and final reports. These two different study designs are complimentary, each with its own strengths. The SCRI design is less impacted by misclassification of COVID-19 vaccine exposure and confounding by time-fixed characteristics, while the cohort study design enables a longer follow-up period.

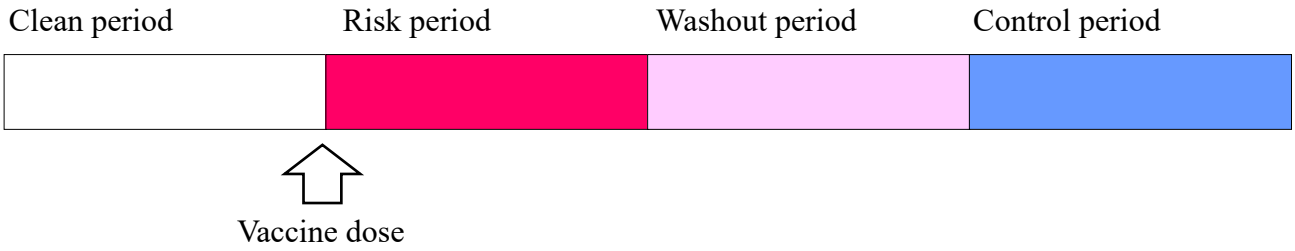
Table 1. Study design and data sources for interim and final reporting

	Interim Report	**Final Report**
Study Design	SCRI (Section 9.1.1)	SCRI (Section 9.1.1) Cohort (Section 9.1.2)
Data Source	Optum pre-adjudicated claims database (Section 9.4.1)	ORD (adjudicated) database (Section 9.4.2)

9.1.1. SCRI

Phase 1 will monitor the incidence rate of pre-specified safety events of interest in a general population of individuals who receive the COMIRNATY 2023-2024 Formula using an SCRI study design that tracks post-vaccination risk intervals and control (reference) periods for each vaccinated individual. Monitoring will be conducted during a pre-specified risk period immediately following vaccination, and the observed rate of events during this risk period will be compared to that of a control period temporally removed from the vaccination event. As depicted in Figure 1, only individuals who receive the COMIRNATY 2023-2024 Formula will be included in the SCRI study (Baker et al., 2015). Within each individual, outcomes occurring during the risk interval will be compared with those occurring during the control period, in order to determine whether these outcomes occur more frequently immediately after vaccination as compared with a reference period. A washout period may be inserted between the risk interval and the control period to ensure that events relating to the vaccine are not incorrectly attributed to the control period. To ensure that observed outcomes are truly incident, a period free from the outcome of interest (clean period) may be required prior to vaccination.

Figure 1. Self-controlled risk interval design



Certain individuals (i.e., immunocompromised patients aged 6 months through 11 years; FDA, 2023b) may receive more than one dose of the COMIRNATY 2023-2024 Formula and thus may have multiple risk and control periods. For these individuals, analysis may be conducted using the first dose and repeated by pooling the multiple risk periods, as well as the control periods.

The safety outcomes of interest, along with relevant clean windows, risk intervals, and washout and control periods, are listed in Section 9.3.2.

9.1.2. Cohort Design

Phase 2 will consist of a propensity score-matched cohort study of individuals with and without a recorded dose of the COMIRNATY 2023-2024 Formula, conducted within the ORD. During the accrual period of 11 September 2023 through 31 March 2024, individuals who receive the COMIRNATY vaccine will be classified as exposed, and those with no recorded vaccination with the COMIRNATY 2023-2024 Formula but who have a healthcare encounter will be classified as comparators. Propensity score matching will be performed to address control of potential confounding, with matching to be conducted within age group and calendar periods. Age group will be defined as: 6 months–4 years; 5–11 years; 12–17 years; 18–64 years; and ≥ 65 years, while calendar periods will be defined by 14-day increments (e.g., 01 September 2023 to 14 September 2023, 15 September 2023 to 28 September 2023). Alternate calendar periods (e.g., one month) may be empirically explored. Thus, within any given calendar period, comparators within the same age group will be matched without replacement to a COMIRNATY recipient on PS, down to a maximum allowable level of precision in the PS (Section 9.7.2.1). This will ensure a sufficient pool of comparators for stratified and/or subpopulation analyses (Sections 9.7.2.3 & 9.7.2.4).

These matched cohorts will be followed for up to one year for occurrence of safety outcomes. For this Phase 2 matched cohort study, the safety outcomes of interest are listed in Section 9.3.2.

9.2. Setting

The source population for this study will consist of all individuals with at least one medical or pharmacy claim from 11 September 2023 through 31 March 2024. The end date of 31 March 2024 was chosen based on the assumption that vaccine uptake will be similar to uptake during the 2022-2023 season. During the 2022-2023 COVID-19 season, the end of March reflected the time when uptake of the bivalent booster was no longer increasing (i.e., most individuals who received the bivalent booster dose had done so prior to March 2023), and COVID-19 cases declined substantially from their peak (CDC, 2020).

Trends in COVID-19 vaccine uptake will be monitored until 30 June 2024 using the Centers for Disease Control and Prevention's (CDC) Weekly COVID-19 Vaccination Dashboard (CDC, 2023d), which publishes estimates of the proportions of children aged 6 months through 17 years and adults 18 years and older who have received a COVID-19 vaccine each week during the 2023-2024 season. If in the final week of reported data for June 2024 these estimates show vaccine uptake in either children or adults that is 1% or greater than the respective estimates reported for the first week of April 2024 (i.e., an increasing trend in COVID-19 vaccine uptake from the first week of April 2024 to the last week of June 2024), then the Sponsor will extend the end date of the accrual period into October 2024, and the updated source population will be reflected in the final study report. This date reflects the latest accrual date that still allows for meeting of the current study milestones. This revision, if needed, will be communicated to the FDA as a protocol amendment.

Each study design will have its own inclusion and exclusion criteria, as listed below.

9.2.1. SCRI

9.2.1.1. Inclusion Criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in Phase 1 of the study:

1. Receive at least one dose of the COMIRNATY 2023-2024 Formula from the date of the COMIRNATY 2023-2024 product launch through 31 March 2024.
2. Age ≥ 6 months when receiving their first recorded dose of the COMIRNATY 2023-2024 Formula.
3. Have continuous medical and pharmacy insurance coverage in the 365 days prior to their vaccination date (as defined in Section 9.2.3), or since birth if the vaccination occurred at < 1 year of age.
4. Experience a safety outcome of interest during a risk interval or control period (on or after vaccination, as defined in Section 9.3.2).
5. Do not experience the safety outcome of interest during the clean period (prior to vaccination, as defined in Section 9.3.2).

9.2.1.2. Exclusion Criteria

Patients meeting any of the following criteria will not be included in Phase 1 of the study:

1. Are of unknown sex.
2. Have a missing month and year of birth.
3. Have received a COVID-19 vaccine in the 270 days prior to the vaccination date (as defined in Section 9.2.3).
4. Have received a COVID-19 vaccine other than the COMIRNATY 2023-2024 Formula on the same vaccination date (defined in Section 9.2.3).

9.2.2. Cohort Study

9.2.2.1. Inclusion Criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in Phase 2 of the study:

1. Age ≥ 6 months on the day of receiving their first recorded dose of the COMIRNATY 2023-2024 Formula (if a vaccine recipient), or on the day they experience a healthcare encounter (if a comparator), defined as the cohort entry date (Section 9.2.3).
2. Have continuous medical and pharmacy insurance coverage in the 365 days prior to the cohort entry date, or since birth if the cohort entry date occurred at < 1 year of age.

9.2.2.2. Exclusion Criteria

Patients meeting any of the following criteria will not be included in Phase 2 of the study:

1. Are of unknown sex.
2. Have a missing month and year of birth.
3. Have received a COVID-19 vaccine in the 270 days prior to cohort entry date (as defined in Section 9.2.3).
4. Have received both the COMIRNATY 2023-2024 Formula and a COVID-19 vaccine other than the COMIRNATY 2023-2024 Formula on the cohort entry date (defined in Section 9.2.3).

In both phases of the study, when creating the analytic population for each specific safety outcome of interest, individuals will be excluded if they experienced that safety outcome during the portion of the baseline period designated as the clean period (Section 9.2.4).

9.2.3. Vaccination Date and Cohort Entry Date

In the Phase 1 SCRI analysis, the date of first vaccination with the COMIRNATY 2023-2024 Formula will be set as the vaccination date. For the analysis assessing individuals who receive more than one dose of the COMIRNATY 2023-2024 Formula, each vaccination with the COMIRNATY 2023-2024 Formula will be set as a new vaccination date.

In the Phase 2 cohort analysis, the cohort entry date will be the date individuals in the COMIRNATY group receive their first recorded dose of the COMIRNATY 2023-2024 Formula. For individuals in the comparator cohort, the cohort entry date will be set as the date of first qualifying healthcare encounter. Propensity score-matched comparators will also be matched on age group and calendar time. Regarding age, matching will be performed between patients within age groups (e.g., 6 months–4 years, 5–11 years, 12–17 years, 18–64 years, and ≥ 65 years). Regarding calendar time, patients will be matched within 14-day windows (e.g., 01 September 2023 to 14 September 2023, 15 September 2023 to 28 September 2023) in which individuals in the exposed cohort will have received vaccination with the COMIRNATY 2023-2024 Formula and individuals in the unexposed cohort will have had a healthcare encounter but no recorded vaccination with the COMIRNATY 2023-2024 Formula. Alternate calendar periods (e.g., one month) may be empirically explored.

For matched comparators, the cohort entry date will be the date within the matched 14-day calendar period on which they had a healthcare encounter.

9.2.4. Baseline Period

The baseline period will consist of all continuously enrolled available time up to one year (365 days) prior to the vaccination date (SCRI) or cohort entry date (cohort study). Recognizing that narrower or specific windows of assessment may better capture select patient attributes of interest, specific covariates may be assessed using alternate time period(s). In this study, all individuals are required to have a minimum of 365 days of continuous health plan enrollment prior to the vaccination or cohort entry date (Sections 9.2.1.1 and 9.2.2.1), or continuous enrollment since birth if the vaccination or cohort entry date occurred at < 1 year of age.

In both study designs, some or all of the baseline period will be used to exclude individuals with prevalent outcomes prior to vaccination or cohort entry date. This portion of the baseline period will be referred to as the ‘clean period.’ For a list of outcome-specific clean periods, please see Section 9.3.2.

9.2.5. Follow-Up Period

9.2.5.1. SCRI

In the SCRI analysis, follow-up for the risk period will begin upon (for the outcomes of anaphylaxis and convulsions/seizures) or one day after (for all other outcomes) receipt of the COMIRNATY 2023-2024 Formula (Table 2) and continue until the earliest of:

- Receipt of a COVID-19 vaccine other than the COMIRNATY 2023-2024 Formula;
- The end of the outcome-specific risk interval as defined in Section 9.3.2;
- Disenrollment from the health plan, death, or the end of data collection.

After the outcome-specific pre-specified washout period following the risk interval, follow-up for the control period will begin and continue until the earliest of:

- Receipt of a COVID-19 vaccine other than the COMIRNATY 2023-2024 Formula;
- The end of the control period as defined in Section 9.3.2;
- Disenrollment from the health plan, death, or the end of data collection.

Individuals will be followed for each safety outcome during both the risk and control periods, such that events observed during the risk period or washout period will not censor follow-up for the control period.

9.2.5.2. Cohort Study

In the cohort study (Phase 2), depending on the safety outcome of interest, follow-up will begin on cohort entry or the day following cohort entry (Table 2) and extend until the earliest of:

- The occurrence of an outcome of interest (Section 9.3.2);
- For COMIRNATY 2023-2024 Formula recipients, receipt of a COVID-19 vaccine other than the COMIRNATY 2023-2024 Formula; for comparators whose qualifying healthcare encounter is for a non-COMIRNATY 2023-2024 Formula COVID-19 vaccination, receipt of a different brand of COVID-19 vaccine from cohort entry;
- One year after cohort entry;
- Disenrollment from the health plan, death, or the end of data collection;

Those comparators who later receive a dose of COMIRNATY 2023-2024 Formula may be eligible for inclusion in the COMIRNATY 2023-2024 Formula cohort if they meet the eligibility criteria for cohort entry.

9.3. Variables

9.3.1. Exposures

9.3.1.1. COMIRNATY 2023-2024 Formula

The SCRI analysis and the cohort analysis will include individuals with exposure to the COMIRNATY 2023-2024 Formula. The code list to define exposure is available in Annex 2 (Appendix I).

9.3.1.2. Comparator Cohort

The Phase 2 cohort study will include comparators with no recorded vaccination for the COMIRNATY 2023-2024 Formula. To improve comparability with the COMIRNATY 2023-2024 Formula vaccinated cohort, patients included in the comparator cohort will be required to have a code indicative of a healthcare encounter, including one of the following:

- Presence of a code for a vaccine other than the COMIRNATY 2023-2024 Formula;
- Presence of a code indicative of an outpatient healthcare encounter.

Codes relating to other vaccines or outpatient visits are provided in Annex 2 (Appendix II).

9.3.2. Outcomes

In both the SCRI and cohort studies, the pre-specified safety outcomes of interest will include the following:

- ADEM
- Anaphylaxis
- Bell's palsy
- CVST
- Convulsions/seizures (non-febrile)
- Encephalomyelitis
- Glomerulonephritis
- Guillain-Barré syndrome
- Herpes zoster
- Immune-mediated myositis
- Immune thrombocytopenia
- Kawasaki disease
- Multi inflammatory syndrome (in children and adults)
- MS
- MI
- Myocarditis/pericarditis
- PE
- Stroke, hemorrhagic
- Stroke, ischemic
- Transverse myelitis

In addition, in Phase 2 of the study, the following pregnancy outcomes will be assessed in pregnant women or their infants, if sample size permits:

- Spontaneous abortion
- Stillbirth
- Preterm birth
- Major congenital malformations
- Small for gestational age

Code lists for the safety outcomes of interest are provided in Annex 2 (Appendix III). Corresponding site of care requirements are listed in Table 2. When possible, outcomes will be defined using a validated claims-based algorithm with high performance (CBER, 2021).

If a safety signal is detected in the interim report, then medical records will be retrieved for a subset of participants to confirm the presence of that study outcome. A safety signal that requires confirmation through medical record review will be defined as a rate ratio of > 3.0 and a corresponding P value of < 0.01 in the primary analysis of the SCRI design (details in Section 9.7.1.1). Additionally, medical record review may be conducted for analyses beyond the primary SCRI analysis if a safety signal (defined as a rate ratio of > 3.0 and a corresponding P value of < 0.01) is detected in the interim or final report. Medical records may also be retrieved for AESIs with estimates approaching the pre-specified safety signal threshold.

Table 2. Clean periods and risk intervals for safety outcomes of interest

Outcome	Clean Period*	Vaccine Risk Interval*	Care Setting**
Acute disseminated encephalomyelitis	Days -28 to -1	Days 0 to 21	IP
Anaphylaxis	Days -30 to -1	Days 0 to 1	IP, ED
Bell's palsy	Days -183 to 0	Days 1 to 42	IP, OP
Cerebral venous sinus thrombosis	Days -365 to 0	Days 1 to 28	IP, OP
Convulsions/seizures, non-febrile	Days -42 to -1	Days 0 to 21	IP, OP
Encephalomyelitis	Days -183 to 0	Days 1 to 42	IP
Glomerulonephritis	Days -365 to 0***	Days 1 to 42***	IP, OP
Guillain-Barré syndrome	Days -365 to 0	Days 1 to 42	IP-primary position only
Herpes zoster	Days -270 to 0	Days 1 to 30	IP, OP
Immune-mediated myositis	Days -365 to 0***	Days 1 to 28	IP, OP
Immune thrombocytopenia	Days -365 to 0	Days 1 to 42	IP, OP
Kawasaki disease	Days -365 to 0	Days 1 to 21	IP, OP
Multi inflammatory syndrome	Days -365 to 0	Days 1 to 42	IP, ED
Multiple sclerosis	Days -365 to 0	Days 1 to 42***	IP, OP
Myocardial infarction	Days -365 to 0	Days 1 to 28	IP
Myocarditis/pericarditis	Days -365 to 0	Days 1 to 21	IP, OP

Table 2. Clean periods and risk intervals for safety outcomes of interest

Outcome	Clean Period*	Vaccine Risk Interval*	Care Setting**
Pulmonary embolism	Days -365 to 0	Days 1 to 28	IP, OP
Stroke, hemorrhagic	Days -365 to 0	Days 1 to 28	IP
Stroke, ischemic	Days -365 to 0	Days 1 to 28	IP
Transverse myelitis	Days -365 to 0	Days 1 to 42	IP, ED

*Expressed in relation to the day of vaccination or cohort entry (Day 0). When more than one vaccine risk interval had been cited in the prior literature, the present risk interval was chosen from the prior literature using the following order of priority for all outcomes other than myocarditis/pericarditis: 1) CBER 2021; 2) the most frequently cited risk interval in prior literature; and 3) the shortest risk interval cited in prior literature. The risk interval for myocarditis/pericarditis was chosen based on CBER 2022.
**IP, Inpatient; ED, Emergency department visit; OP, Outpatient facility claims and professional/provider claims.
***Could not be determined from the literature, so modeled after other outcome intervals in CBER 2021.

9.3.2.1. Outcome-Specific Risk and Control Periods

The SCRI design (Section 9.1.1) requires that clean periods, risk intervals, washout periods, and control intervals be specified for every study outcome. The lengths of the clean periods and risk intervals are listed in Table 2. The washout period for all outcomes will begin immediately after the end of the risk interval and continue for 30 days (Akpandak et al., 2022); the control period will follow the washout period and be equivalent in length to the risk interval. Interval lengths were determined based on prior vaccine literature, including COVID-19 vaccine studies conducted as part of the FDA's Center for Biologics Evaluation and Research (CBER) Biologics Effectiveness and Safety (BEST) System (Akpandak et al., 2022; Barda et al., 2021; CBER, 2021; Joy et al., 2023; Klein et al., 2021; Liu et al., 2023; Martin et al., 2021; McCarthy et al., 2013; Wack et al., 2021).

9.3.3. Covariates

All members of the study cohorts will be described according to covariates identified in the claims data. Demographic attributes will be determined on the vaccination/cohort entry date, while other factors will be assessed in the one year prior to the cohort entry date. Unless specified as for descriptive purposes only, the covariates listed will be included in the PS models. All variables are binary unless otherwise specified.

Demographic Attributes

- Sex
- Age (categorical); for the purposes of matching the exposed and unexposed cohorts in Phase 2, we will use the following age groups: 6 months–4 years, 5–11 years, 12–17 years, 18–64 years, and ≥ 65 years
- Calendar month of the vaccination date or cohort entry date (categorical)
- Geographic region (categorical)

Comorbidities

- Asthma
- Non-malignant blood disorders, including sickle cell disease
- Chronic lung disease, including chronic obstructive pulmonary disease (COPD)
- Down syndrome
- Heart disease
- History of SARS-CoV-2 infection
- Immunocompromised status (i.e., history of human deficiency virus [HIV]; organ, bone marrow or stem cell transplant; use of immunosuppressant medication)
- Kidney disorders, including chronic kidney disease
- Liver disorders
- Neurological or neurodevelopmental conditions
- Malignant neoplasms
- Obesity
- Type 2 diabetes

Prior COVID-19 Vaccination – Descriptive only (not for inclusion in PS model)

- Receipt of COVID-19 vaccine doses (any brand) prior to 2023-2024
    - Because COVID-19 vaccination in the 270 days prior to cohort entry is an exclusion criterion (Section 9.2.2.2), this variable will only capture COVID-19 vaccinations in the 365 days through 271 days prior to cohort entry
- Days from the most recent prior COVID-19 vaccine dose (any brand) to first vaccination with 2023-2024 formulations (for all Phase 1 individuals, as well as Phase 2 individuals receiving COMIRNATY or another 2023-2024 formulation)

Healthcare Utilization

- Number of hospitalizations in prior year (continuous)
- Number of emergency room visits in prior year (continuous)
- Number of outpatient encounters in prior year (continuous)
- Other recorded vaccines administered
    - Seasonal influenza
    - RSV

Medication History

- Systemic immunomodulators
- Oral corticosteroids
- Antivirals
- Antibiotics

In addition to the covariates listed above, baseline attributes will be identified on an empiric basis by examining the 25 most frequently occurring diagnoses, drugs dispensed, and procedures (including other baseline vaccinations, as captured through NDC and CPT codes) performed among individuals with and without COMIRNATY 2023-2024 Formula exposure.

These empiric covariates will be considered for inclusion in the PS models if they are potential confounders.

COVID-19 Vaccination – Descriptive only (not for inclusion in PS model)

- Site of vaccination (e.g., outpatient, pharmacy)
- Source of vaccination information (e.g., CPT code[1], NDC)
- Number of doses prior to 2023-2024, by vaccine product
- Average number of days between doses of COMIRNATY 2023-2024 Formula, among those with multiple doses

Code lists for covariates are included in Appendix IV.

9.4. Data Sources

The patients included in this study will be drawn from the Optum pre-adjudicated claims database for the interim reporting to expedite the identification of vaccinated patients, and from the ORD for the final reporting. These data sources are described below.

9.4.1. Optum Pre-Adjudicated Claims Database

The database includes pre-adjudicated medical claims, supplemented with adjudicated pharmacy claims and health plan enrollment information. As claims for pharmacy services are typically submitted electronically by the pharmacy at the time prescriptions are filled or vaccinations are administered and are updated in the underlying database on a weekly basis, they are not included in the pre-adjudicated feed. The pre-adjudicated medical claims encompass hospital and physician claims that are submitted and processed daily from a large US commercial health plan. The individuals included in the pre-adjudicated medical claims database are fully insured by the health plan, which provides reimbursement of medical and pharmacy services regardless of site of care, and individuals are geographically diverse within the US. The claims adjudication process involves numerous assessments and adjustments and may result in claims being returned to the provider for revision or sent for payment processing. The pre-adjudicated claims are maintained in a database that allows for the capture of up to three years of prior data. These pre-adjudicated claims have been used for research previously, and for federally funded public health surveillance (Dore et al., 2012; FDA, 2021b; Shoaibi et al., 2023; Wong et al., 2023; Moll et al., 2023; Schneider et al., 2023).

The data include demographics, details from pharmacy claims (reflecting dispensings), and all pre-adjudicated medical and facility claims, including information on the types of services

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or procedures and their accompanying diagnoses. The coding of medical claims conforms to insurance industry standards, including:

- Use of designated claims forms (e.g., physicians use the CMS-1500 format and hospitals use the UB-04 format)
- International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes and procedure codes
- Current Procedural Terminology (CPT-4®)[2] codes
- Centers for Medicare and Medicaid Services (CMS) HCPCS codes

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

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

9.4.2. Optum Research Database

The ORD is a proprietary research database containing eligibility and adjudicated pharmacy and medical claims data from a large US health plan affiliated with Optum. The individuals covered by this health plan are geographically diverse across the US. As early as 1993, medical and pharmacy claims data are available for 70 million individuals with both medical and pharmacy benefit coverage. In 2021, data were available for approximately 12.6 million individuals with medical and pharmacy coverage. Optum research activities use de-identified data from the research database. 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.

9.5. Study Size

The sample size achieved will depend on the number of recipients of the COMIRNATY 2023-2024 Formula in the databases. All individuals who meet the study's eligibility criteria during the study period will be included.

9.6. Data Management

All analyses will be conducted using Statistical Analysis System (SAS) version 9.4 (SAS Institute Inc., Cary, North Carolina) and SAS Enterprise Guide 6.1 or later. The data will be

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extracted once per report. All reports will utilize the structured data only. The interim report will include summarized results from the Optum pre-adjudicated claims database described in Section 9.4.1. The final report will include results summarized from the ORD as described in Section 9.4.2. The characteristics of patients to be included in each data extract (e.g., required vaccine codes) and the specific timeframes of each data extract will reflect the study inclusion/exclusion criteria described in Section 9.2, the baseline and follow-up periods in Sections 9.2.4 and 9.2.5, and the study variables in Section 9.3. All reports and deliverables will contain aggregated results only and will not identify individual patients, physicians, or facilities.

9.7. Data Analysis

9.7.1. SCRI

9.7.1.1. Primary Analysis

Descriptive statistics will be used to summarize the baseline characteristics of those who receive the COMIRNATY 2023-2024 Formula. Counts of each safety outcome of interest will be reported within pre-specified risk and control windows. Then, the observed incidence rates of the outcomes of interest will be estimated in the risk window and the control window. Among the individuals who experience an outcome of interest in either the risk window or the control window (but not both), an exact conditional Poisson regression model with the natural logarithm of the person-time as the offset will be used to calculate the relative incidence (rate ratio) and corresponding 95% confidence interval (CI) of the risk period relative to the control period. With the self-controlled design, whereby each individual serves as their own comparator, the analysis accounts for the factors that vary across but not within individuals (i.e., time-invariant covariates).

The results from the SCRI utilizing the Optum pre-adjudicated claims database will be presented in the interim report, while results from the SCRI utilizing the ORD will be presented in the final report.

9.7.2. Cohort Study

9.7.2.1. Propensity Score Modeling and Matching

The COMIRNATY 2023-2024 Formula-exposed and the unexposed comparator cohorts will be created as described in Section 9.2.3. Each cohort member will be described with respect to baseline covariates as listed in Section 9.3.3. These cohort members will be included in the propensity score modeling and matching.

This study will use a single PS model that encompasses risk factors for multiple outcomes, an approach demonstrated in other studies conducted to fulfill post-licensure regulatory commitments and requirements to the FDA and other regulatory agencies (Seeger et al., 2023; Ziyadeh et al., 2020). While not all risk factors may be associated with all outcomes to the same degree, adjusting for covariates that are weakly or not at all associated with a given outcome is expected to result in negligible bias if residual confounding is small (Brookhart et al., 2006; Myers et al., 2011). Incorporating a wide array of outcome predictors

(Section 9.3.3) into the PS is expected to minimize residual confounding, producing groups with similar patterns of both measured and unmeasured factors (Guertin et al., 2016).

The PS model will consist of a logistic regression model that incorporates the pre-specified demographic and comorbidity covariates, healthcare utilization, and calendar month of vaccination or cohort entry as independent variables, and an indicator for receipt of the COMIRNATY 2023-2024 Formula as the dependent variable. Two-way interactions of all variables with calendar month of vaccination or cohort entry, or empirically defined variables that are potential confounders, may also be considered for inclusion in the following model:

$$\text{logit}\{P(T_i = 1 \mid \mathbf{X}_i)\}$$

$$\begin{aligned}
&= \beta_0 + \beta_1 \text{Sex (binary)}_i + \beta_2 \text{Age (categorical)}_i \\
&+ \beta_3 \text{Calendar month (categorical)}_i + \beta_4 \text{Geographic region (categorical)}_i \\
&+ \beta_5 \text{Asthma (binary)}_i + \beta_6 \text{Non-malignant blood disorders (binary)}_i \\
&+ \beta_7 \text{Chronic lung disease (binary)}_i + \beta_8 \text{Down syndrome (binary)}_i \\
&+ \beta_9 \text{Heart disease (binary)}_i \\
&+ \beta_{10} \text{History of SARS-CoV-2 infection (binary)}_i \\
&+ \beta_{11} \text{Immunocompromised status (binary)}_i \\
&+ \beta_{12} \text{Kidney disorders (binary)}_i + \beta_{13} \text{Liver disorders (binary)}_i \\
&+ \beta_{14} \text{Neurological or neurodevelopmental conditions (binary)}_i \\
&+ \beta_{15} \text{Malignant neoplasms (binary)}_i + \beta_{16} \text{Obesity (binary)}_i \\
&+ \beta_{17} \text{Type II diabetes (binary)}_i \\
&+ \beta_{18} \text{Number of hospitalizations in prior year (continuous)}_i \\
&+ \beta_{19} \text{Number of emergency room visits in prior year (continuous)}_i \\
&+ \beta_{20} \text{Number of outpatient encounters in prior year (continuous)}_i \\
&+ \beta_{21} \text{Seasonal influenza vaccination (binary)}_i \\
&+ \beta_{22} \text{RSV vaccination (binary)}_i + \beta_{23} \text{Systemic immunomodulators (binary)}_i \\
&+ \beta_{24} \text{Oral corticosteroids (binary)}_i + \beta_{25} \text{Antivirals (binary)}_i \\
&+ \beta_{26} \text{Antibiotics (binary)}_i + \beta_{27} \text{Identified empiric variables (binary)}_i,
\end{aligned}$$

where $T_i$denotes exposure status for individual i, with $T_i = 1$ indicating a recorded vaccination of the COMIRNATY 2023-2024 Formula and $T_i = 0$ indicating no recorded vaccination of the COMIRNATY 2023-2024 Formula.

A greedy digit-based matching algorithm will be used, in which patients exposed to the COMIRNATY 2023-2024 Formula are matched without replacement to comparator patients at a given level of precision defined by the number of digits of the PS (Parsons, 2001), to a maximum of 8 decimal places. When no further matches are available at a given level of precision, the number of digits is sequentially reduced until a maximum allowable caliper of 0.1 is reached, thereby ensuring that the matched cohorts are comparable with respect to the underlying measured risk factors. Matching by propensity score will be conducted within

strata defined by age group and calendar period. A matching ratio (e.g., up to 1:10) may be implemented.

PS matching will produce a single matched cohort (the master cohort) that will be used to conduct all primary, secondary, and sub-group analyses for the study outcomes. Balance between the PS-matched cohorts will be evaluated by overlaying graphs of the PS distributions in COMIRNATY-exposed and comparator cohorts before and after PS matching. Additionally, standardized differences between the PS-matched cohorts for each covariate in the model will also be assessed. Variables with an absolute standardized difference less than 0.1 will be considered balanced (Austin, 2009). If a variable has a standardized difference that is greater than 0.1, further PS model modifications (e.g., addition of interaction terms) or inclusion of the imbalanced covariates in an outcome model will be considered (Normand et al., 2001). If there are confounders identified that would only be appropriate to include for one outcome and not the others, a separate PS model for the specific outcome will be considered.

Outcome-specific exclusion criteria will be applied to the master cohort after PS matching but before the outcome specific analysis; the matched cohort that remains will be the analytic cohort for that specific outcome. The matched comparators of individuals excluded for outcome-specific exclusion criteria will also be excluded from the outcome-specific analysis.

9.7.2.2. Primary Analysis

Once the matched cohorts have been created, the incidence rate of each safety outcome will be estimated among the COMIRNATY 2023-2024 Formula-exposed group and its matched comparator group. The rate ratio will be estimated using unconditional Poisson regression that accounts for both the matching ratio (i.e., a weight representing the number of COMIRNATY 2023-2024 recipients divided by the number of comparators in each individual strata) and individuals who are included in both study cohorts (i.e., using a REPEATED statement with an independent working correlation structure). If standardized differences show covariate imbalances in the matched cohorts, imbalanced covariates will be included in the unconditional Poisson models.

9.7.2.3. Secondary Analysis

The main analysis will compare the occurrence of safety outcomes in the COMIRNATY 2023-2024 Formula-exposed group to that of the matched comparator group. Secondary analyses will conduct this comparison separately, including recalculation of the matching ratio and accounting for individuals who are included in both study cohorts for various subsets of the matched comparator group, including:

- Comparators who, on cohort entry, received a 2023-2024 formulation of a COVID-19 vaccine other than COMIRNATY (i.e., Moderna or Novavax)
- Comparators who received a non-COVID-19 vaccine on cohort entry
- Comparators who did not receive a vaccine on cohort entry but had another type of outpatient health encounter.

9.7.2.4. Subgroup Analysis

If sample size permits, the main analysis will be restricted to the following subgroups:

- Individuals with concomitant administration of a non-COVID-19 vaccine (e.g., seasonal influenza, RSV) on cohort entry date; specific analyses will be performed among individuals receiving seasonal influenza vaccine and those receiving RSV vaccine
- Immunocompromised individuals
- Individuals with specific baseline comorbidities, such as a chronic lung, heart, kidney or liver condition; cancer; Down syndrome or other neurological or neurodevelopmental disorders; and blood disorders
- Individuals with prior SARS-CoV-2 infection
- Individuals with prior COVID-19 vaccination
- Pregnant women
- Individuals aged < 18 years
- Individuals aged ≥ 65 years

For the subgroup analysis, the propensity score will be included in the model as a covariate, given that some matched strata may be broken by restricting both the COMIRNATY 2023-2024 Formula cohort and the comparator cohort by the above attributes. As with the primary analysis, unconditional Poisson regression will be used, and the model will account for individuals who are included in both groups.

Lastly, a descriptive analysis of the matched cohorts will focus specifically on outcomes related to pregnancy (spontaneous abortion, stillbirth, preterm birth, major congenital malformations and small for gestational age). Recipients of the COMIRNATY 2023-2024 Formula and comparators who are pregnant at cohort entry will be identified, and the timing of their vaccination in relation to their last menstrual period (LMP) will be characterized. Baseline characteristics will be descriptively compared among the pregnant COMIRNATY 2023-2024 Formula recipients and comparators. Among COMIRNATY 2023-2024 Formula recipients who are pregnant at cohort entry, as well as among pregnant comparators, the incidence of pregnancy outcomes (spontaneous abortion, stillbirth, preterm birth) during follow-up will be described. For those individuals whose pregnancy results in a live birth, the prevalence of major congenital malformations and small for gestational age in their infants will be descriptively reported. Prevalence estimates will be reported separately for infants whose mothers received the COMIRNATY 2023-2024 Formula when pregnant and infants whose mothers do not have a recorded vaccination of COMIRNATY 2023-2024. Due to the relatively short length of follow-up, comparative analyses relating to pregnancy and infant outcomes will not be performed.

All results from Phase 2 analyses will be presented in the Final Report.

9.8. Quality Control

For the final reporting, this study will use ORD data derived from claims submitted for payment. 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 (Dore et al., 2011; Eng et al., 2012; Laughlin, 2011; Quam et al., 1993).

The study will be carried out according to Optum Epidemiology's internal standard operating procedures (SOPs) that are consistent with the Guidelines for Good Pharmacoepidemiology Practices (GPP) published by the European Medicines Agency (EMA) and International Society for Pharmacoepidemiology (European Medicines Agency, 2017; Public Policy Committee, International Society of Pharmacoepidemiology, 2016) as well as the FDA's Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data (FDA, 2013).

Programming for this project will be conducted by a primary analyst and reviewed by a separate analyst (validation analyst). Validation of all statistical programs and results consists of a combination of visual checks (i.e., examination of the programming log, visual printouts before and after data management steps, etc.) and computational checks (i.e., repeating calculations for comparison purposes) performed by a validation analyst. In addition, an epidemiologist and a senior scientist will perform a substantive review of all study deliverables. All validation and quality control procedures are conducted in accordance with Optum SOPs, which prescribe that processes and deliverables are documented, reviewed, and validated in sufficient detail to allow for subsequent re-examination or replication.

9.9. Limitations of the Research Methods

The proposed project is based on analysis of automated medical and prescription claims, including pre-adjudicated (interim reporting) and fully adjudicated claims (final reporting).

For the interim report, the SCRI analysis will be based on automated and prospectively collected pre-adjudicated medical and adjudicated prescription claims. A strength of pre-adjudicated medical claims is the shorter lag time between the receipt of care and the appearance of the claim, while the accompanying limitation is that these pre-adjudicated claims may be subject to revision during the adjudication process. A limitation of the SCRI design may be its limited ability to assess chronic outcomes such as MS. Thus, the cohort analysis will be used as the primary analysis for chronic outcomes.

While adjudicated claims data are extremely valuable for the efficient and effective examination of healthcare outcomes, treatment patterns, healthcare resource utilization, and costs, all claims databases have certain inherent limitations because the claims are collected for the purpose of payment, not research. 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.

Another limitation of claims data relates to potential misclassification of exposure covariates. For instance, vaccines that are administered as part of a government program or an office-based or school-based vaccination clinic may not be captured in our database if insurance information was not provided during the vaccine encounter. This potential exposure misclassification is minimized in the self-controlled design in Phase 1; misclassification of exposure in Phase 2 would be expected to bias the results towards the null (CDC, 2023e). Furthermore, 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 paid for out-of-pocket, as well as those not dispensed through a pharmacy, will not be observed in the claims data. Similarly, we may not have complete history of comorbidity or treatment for individuals due to switching in health plan insurer.

The study power may be limited by the short duration of accrual and a limited follow-up period, particularly during Phase 1. Because the COMIRNATY 2023-2024 Formula was approved in September 2023, the study may be underpowered to conduct comparisons at the interim report stage.

Lastly, in all observational studies, treatment is not randomly assigned, and there is potential for residual confounding by factors not captured or poorly measured in claims databases. As often used in pharmacoepidemiology, a 1-year covariate assessment period prior to cohort entry will be used to control for potential baseline confounding in Phase 2. Use of a longer covariate assessment period may increase the capture of chronic conditions. However, most individuals with a chronic condition are expected to interact with the healthcare system at least once per year, suggesting that a 1-year covariate assessment period may be sufficient for capturing chronic conditions. Nevertheless, those without a visit in the 1-year baseline period may be missed. Additionally, prior COVID-19 vaccination in the previous year is an important potential confounder, but it could not be included in the propensity score model in Phase 2 due to potential positivity violations. Individuals who received a COVID-19 vaccine in the 270 days prior to cohort entry date will be excluded from the study, so by design, COVID-19 vaccination in the previous year is not an informative variable, as it would only capture COVID-19 vaccination in the 365 days to 271 days prior to receipt of the COMIRNATY 2023-2024 Formula. Finally, receipt of other vaccinations at baseline besides seasonal influenzas vaccines and RSV vaccines will not be included in the propensity score model, which may result in residual confounding. To minimize this potential bias, the most common baseline procedure codes will be examined to identify additional baseline vaccinations that may be potential confounders. Baseline vaccinations other than seasonal vaccination or RSV that are identified during this process will be considered for inclusion in the propensity score model.

A strength of the current study is its incorporation of a self-controlled design, which eliminates the concern of confounding by time-fixed characteristics that vary across individuals. Similarly, in Phase 2, careful PS matching of the COMIRNATY and comparator cohorts is expected to minimize residual confounding in the cohort analysis. Finally, capture

of current COVID-19 vaccines is likely better within the commercially insured population as compared to prior years, when there were more opportunities for individuals to receive a COVID-19 for free without utilizing their insurance (CDC, 2023e).

9.10. Other Aspects

Not applicable.

10. PROTECTION OF HUMAN PARTICIPANTS

10.1. Patient Information

This study involves data that exist in deidentified/anonymized structured format and contains no patient personal information.

10.2. Patient Consent

As this study involves deidentified/anonymized 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)/Ethics Committee (EC)

Optum will prepare and submit the appropriate documents to a central IRB for Optum's conduct of the project. Optum will communicate directly with the IRB to address any questions and/or provide any additional information in connection with the review. Pfizer shall provide any necessary assistance or documents required for the submission to the IRB. Approval from an IRB for this project is not guaranteed. This project will be undertaken only after the study combined protocol/SAP has been approved by the IRB or granted an Exemption Determination Letter from the IRB. The IRB will monitor the study for the life of the project and may require formal re-review and approval on an annual basis. Changes to the project may also require re-review and approval by the IRB.

There must be prospective approval of the study protocol/SAP, protocol/SAP amendments, and other relevant documents (e.g., informed consent forms if applicable) from the relevant IRBs or ECs. All correspondence with the IRB/EC must be retained. Copies of IRB/EC 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 the following guidance documents:

- Guidelines for GPP. Public Policy Committee, International Society of Pharmacoepidemiology. Pharmacoepidemiology and Drug Safety 2015; 25:2-10;
- International Ethical Guidelines for Epidemiological Studies issued by the Council for International Organizations of Medical Sciences (CIOMS);

- EMA European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology;
- FDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; and
- FDA Guidance for Industry and FDA Staff: Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data.

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, it is not possible to link (i.e., identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an adverse event (AE) (i.e., 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 (e.g., clinical hold) by an applicable competent authority in any area of the world, or if Optum becomes aware of any new information which might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately.

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14. LIST OF TABLES

15. LIST OF FIGURES

16. ANNEX 1. LIST OF STANDALONE DOCUMENTS

None.

17. ANNEX 2. CODE LISTS

17.1. Appendix I – COMIRNATY 2023-2024 Formula

The following CPT and NDC codes are sourced from the Immunization Information Systems (IIS) at the Center for Disease Control and Prevention (CDC, 2023b). Other codes will be included as they become available.

17.1.1. CPT Codes

91318	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 3 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
91319	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 10 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
91320	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use

17.1.2. NDC Codes

00069-2362-01 Ages 12 years and older; VIAL, SINGLE-DOSE, 30 mcg/0.3 mL

00069-2392-01 Ages 12 years and older; SYRINGE, PRE-FILLED, 30 mcg/0.3 mL

59267-4331-01 Ages 5 through 11 years; VIAL, SINGLE-DOSE, 10 mcg/0.3 mL

59267-4315-01 Ages 6 months through 4 years; VIAL, MULTI-DOSE, 3 DOSES, 3mcg / 0.3 mL AFTER DILUTION

17.2. Appendix II – Comparator Codes

17.2.1. COVID-19 Vaccine 2023-2024 Formulations Other than the COMIRNATY 2023-2024 Formula

17.2.1.1. Moderna Spikevax

17.2.1.1.1. CPT Codes[3]

91322 -- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 50 mcg/0.5 mL dosage, for intramuscular use

91321 -- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 25 mcg/0.25 mL dosage, for intramuscular use

17.2.1.1.2. NDC Codes

80777-0102-04 -- Ages 12 years and older; VIAL, SINGLE-DOSE, 50 mcg/ 0.5 mL

80777-0102-01 -- Ages 12 years and older; SYRINGE, PRE-FILLED, 50 mcg/ 0.5 mL

80777-0287-07 -- v25 mL

17.2.1.2. Novavax COVID-19 Vaccine, Adjuvanted

17.2.1.2.1. CPT codes

91304 -- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL dosage, for intramuscular use

0041A -- Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL

0042A -- Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL

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0044A -- Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL

17.2.1.2.2. NDC Codes

80631-0105-01 -- Ages 12 years and older; VIAL, MULTI-DOSE, 5 DOSES, 5 mcg/0.5 mL

17.2.2. Other Vaccines

CPT and NDC codes are sourced from the Immunization Information Systems (IIS) at the Center for Disease Control and Prevention (CDC, 2023c). Other codes will be included as they become available.

17.2.2.1. CPT Codes[4]

90630, 90653-90664, 90666-90668, 90672-90674, 90682-90689, 90694, 90724, 90756	Influenza virus vaccine
90380-90381, 90678-90679, 96380-96381	Respiratory syncytial virus vaccine
90470	H1N1 immunization
90476-90477	Adenovirus vaccine
90581	Anthrax vaccine
90585, 90728	Tuberculosis BGC vaccine
90611, 90622	Smallpox/monkeypox vaccine
90619-90621, 90644, 90733-90734	Meningococcal vaccine
90625, 90725	Cholera vaccine
90626-90627, 90738	Tick-borne/Japanese encephalitis virus vaccine
90632-90636, 90730	Hepatitis A vaccine

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90636, 90739-90740, 90743-90748, 90759, 90731[5]	Hepatitis B vaccine
90645-90648, 90737	Hemophilus influenza type B vaccine
90649-90651	Human Papillomavirus vaccine
90665	Lyme disease vaccine
90669-90671, 90732	Pneumococcal vaccine
90675-90676, 90726	Rabies vaccine
90680-90681	Rotavirus vaccine
90690-90693	Typhoid vaccine
90696-90702, 90714-90715, 90720-90723	Diphtheria vaccine
90696-90703, 90714-90715, 90723	Tetanus vaccine
90696-90698, 90700, 90715, 90723	Pertussis vaccine
90704, 90707, 90709-90710	Mumps vaccine
90705, 90707-90708, 90710	Measles vaccine
90706, 90707-90710	Rubella vaccine
90696-90698, 90712-90713	Poliovirus vaccine
90710, 90716	Varicella virus vaccine
90717	Yellow fever vaccine
90727	Plague vaccine
90736, 90750	Zoster (shingles) vaccine
90758	Ebolavirus vaccine
90584, 90587	Dengue vaccine

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17.2.2.2. NDC Codes

The below list includes generic vaccine names classified by therapeutic use. Codes for generic vaccines are based on the Hierarchical Ingredient Code List (HICL) system proprietary to First Databank. All associated NDC codes will be utilized. Other vaccines will be included as they become available.

Adenovirus vaccine, live

Anthrax vaccine

Anthrax vaccine, adsorbed

BCG vaccine

BCG vaccine, live

Cholera vaccine

Dengue vaccine

Diphtheria, pertussis, tetanus, and haemophilis influenzae type B vaccine

Hepatitis A virus vaccine

Hepatitis A virus and hepatitis B virus vaccine

Hepatitis B and haemophilus influenzae type B vaccine

Hepatitis B, diphtheria, and poliomyelitis virus vaccine

Hepatitis B, haemophilus influenzae type B, and meningococcal vaccine

Hepatitis B virus vaccine

HPV vaccine

Influenza A (H1N1) vaccine

Influenza A (H1N1) vaccine, live

Influenza virus vaccine

Influenza virus vaccine, trivalent

Influenza virus vaccine, trivalent, live

Japanese encephalitis vaccine

Measles and rubella vaccine

Measles, mumps, and rubella vaccine

Measles vaccine, live, attenuated

Mumps vaccine, live

Plague vaccine

Poliomyelitis vaccine, killed

Poliomyelitis vaccine, live

Rabies vaccine

Rabies vaccine, human diploid

Rotavirus vaccine, live

Rubella and mumps vaccine

Rubella vaccine

Smallpox, monkeypox, live

Smallpox vaccine, live

Staphylococcus vaccine

Typhoid vaccine

Varicella virus vaccine, live

Yellow fever vaccine

Zoster vaccine, live

17.2.3. Outpatient Codes

CPT Codes[6]	
99201-99205	Outpatient physician evaluation and management
99211-99215	
99241-99245	
99354-99355	
99381-99387[7]	
99391-99397	

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17.3. Appendix III – Safety Outcomes of Interest

All codes are ICD-10 diagnosis codes; all outcomes will be defined based on the presence of a single code unless otherwise specified. In order to qualify as an outcome, the outcome-specific codes must be identified during emergency department visits, inpatient hospitalizations, or outpatient visits, as detailed in Table 2. Outpatient visits are defined through physician evaluation and management codes (Section 17.2.3).

* Outcome codes marked with an asterisk are based on COVID-19 vaccine studies conducted as part of the FDA's CBER BEST system.

- Acute disseminated encephalomyelitis (ADEM)*
    - G04.00 – Acute disseminated encephalitis and encephalomyelitis, unspecified
- Anaphylaxis*
    - T80.52XA – Anaphylactic reaction due to vaccination, initial encounter
    - T78.2XXA – Anaphylactic shock, unspecified, initial encounter
- Bell's palsy*
    - G51.0 – Bell's palsy
    - G51.8 – Other disorders of facial nerve
    - G51.9 – Disorder of facial nerve, unspecified
- Cerebral venous sinus thrombosis (CVST)
    - I67.6 – Nonpyogenic thrombosis of intracranial venous system
    - I63.6 – Cerebral infarction due to cerebral venous thrombosis, nonpyogenic
- Convulsions/seizures (non-febrile)
    - G40.001 – Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
    - G40.009 – Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
    - G40.011 – Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
    - G40.019 – Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
    - G40.101 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus

- G40.109 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
- G40.111 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
- G40.119 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
- G40.201 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
- G40.209 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
- G40.211 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
- G40.219 – Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
- G40.301 – Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
- G40.309 – Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
- G40.311 – Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
- G40.319 – Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
- G40.401 – Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
- G40.409 – Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
- G40.411 – Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
- G40.419 – Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
- G40.501 – Epileptic seizures related to external causes, not intractable, with status epilepticus

- G40.509 – Epileptic seizures related to external causes, not intractable, without status epilepticus
- G40.801 – Other epilepsy, not intractable, with status epilepticus
- G40.802 – Other epilepsy, not intractable, without status epilepticus
- G40.803 – Other epilepsy, intractable, with status epilepticus
- G40.804 – Other epilepsy, intractable, without status epilepticus
- G40.811 – Lennox-Gastaut syndrome, not intractable, with status epilepticus
- G40.812 – Lennox-Gastaut syndrome, not intractable, without status epilepticus
- G40.813 – Lennox-Gastaut syndrome, intractable, with status epilepticus
- G40.814 – Lennox-Gastaut syndrome, intractable, without status epilepticus
- G40.821 – Epileptic spasms, not intractable, with status epilepticus
- G40.822 – Epileptic spasms, not intractable, without status epilepticus
- G40.823 – Epileptic spasms, intractable, with status epilepticus
- G40.824 – Epileptic spasms, intractable, without status epilepticus
- G40.89 – Other seizures
- G40.901 – Epilepsy, unspecified, not intractable, with status epilepticus
- G40.909 – Epilepsy, unspecified, not intractable, without status epilepticus
- G40.911 – Epilepsy, unspecified, intractable, with status epilepticus
- G40.919 – Epilepsy, unspecified, intractable, without status epilepticus
- G40.A01 – Absence epileptic syndrome, not intractable, with status epilepticus
- G40.A09 – Absence epileptic syndrome, not intractable, without status epilepticus
- G40.A11 – Absence epileptic syndrome, intractable, with status epilepticus
- G40.A19 – Absence epileptic syndrome, intractable, without status epilepticus
- G40.B01 – Juvenile myoclonic epilepsy, not intractable, with status epilepticus
- G40.B09 – Juvenile myoclonic epilepsy, not intractable, without status epilepticus
- G40.B11 – Juvenile myoclonic epilepsy, intractable, with status epilepticus
- G40.B19 – Juvenile myoclonic epilepsy, intractable, without status epilepticus
- R56.1 – Post traumatic seizures
- R56.9 – Unspecified convulsions

- Encephalomyelitis*
    - G04.02 – Postimmunization acute disseminated encephalitis, myelitis, and encephalomyelitis
    - G04.00 – Acute disseminated encephalitis and encephalomyelitis, unspecified
    - G04.81 – Other encephalitis and encephalomyelitis
    - G04.90 – Encephalitis and encephalomyelitis
    - G05.3 – Encephalitis and encephalomyelitis in diseases classified elsewhere
- Glomerulonephritis
    - N06.A Isolated proteinuria with C3 glomerulonephritis
    - N06.7 Isolated proteinuria with diffuse crescentic glomerulonephritis
    - N06.5 Isolated proteinuria with diffuse mesangiocapillary glomerulonephritis
    - N06.4 Isolated proteinuria with diffuse endocapillary proliferative glomerulonephritis
    - N04.A Nephrotic syndrome with C3 glomerulonephritis
    - N04.2 Nephrotic syndrome with diffuse membranous glomerulonephritis
    - N04.7 Nephrotic syndrome with diffuse crescentic glomerulonephritis
    - N04.5 Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis
    - N04.3 Nephrotic syndrome with diffuse mesangial proliferative glomerulonephritis
    - N04.4 Nephrotic syndrome with diffuse endocapillary proliferative glomerulonephritis
    - N05.A Unspecified nephritic syndrome with C3 glomerulonephritis
    - N05.7 Unspecified nephritic syndrome with diffuse crescentic glomerulonephritis
    - N05.2 Unspecified nephritic syndrome with diffuse membranous glomerulonephritis
    - N05.5 Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
    - N03.A Chronic nephritic syndrome with C3 glomerulonephritis
    - N03.7 Chronic nephritic syndrome with diffuse crescentic glomerulonephritis
    - N03.2 Chronic nephritic syndrome with diffuse membranous glomerulonephritis
    - N03.5 Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis

  - N00.A Acute nephritic syndrome with C3 glomerulonephritis
  - N00.2 Acute nephritic syndrome with diffuse membranous glomerulonephritis
  - N00.5 Acute nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
  - N00.7 Acute nephritic syndrome with diffuse crescentic glomerulonephritis
  - N07.A Hereditary nephropathy, not elsewhere classified with C3 glomerulonephritis
  - N02.7 Recurrent and persistent hematuria with diffuse crescentic glomerulonephritis
  - N02.A Recurrent and persistent hematuria with C3 glomerulonephritis
- Guillain-Barré syndrome*
  - G61.0 – Guillain-Barré syndrome
- Herpes zoster
  - B02.* Zoster [herpes zoster]
- Immune-mediated myositis
  - G72.41 – Inclusion body myositis [IBM]
  - M33 – Dermatopolymyositis
  - M33.0 – Juvenile dermatomyositis
  - M33.00 – Juvenile dermatomyositis, organ involvement unspecified
  - M33.01 – Juvenile dermatomyositis with respiratory involvement
  - M33.02 – Juvenile dermatomyositis with myopathy
  - M33.03 – Juvenile dermatomyositis without myopathy
  - M33.09 – Juvenile dermatomyositis with other organ involvement
  - M33.1 – Other dermatomyositis
  - M33.10 – Other dermatomyositis, organ involvement unspecified
  - M33.11 – Other dermatomyositis with respiratory involvement
  - M33.12 – Other dermatomyositis with myopathy
  - M33.13 – Other dermatomyositis without myopathy
  - M33.19 – Other dermatomyositis with other organ involvement
  - M33.2 – Polymyositis
  - M33.20 – Polymyositis, organ involvement unspecified
  - M33.21 – Polymyositis with respiratory involvement
  - M33.22 – Polymyositis with myopathy

- M33.29 – Polymyositis with other organ involvement
- M33.9 – Dermatopolymyositis, unspecified
- M33.90 – Dermatopolymyositis, unspecified, organ involvement unspecified
- M33.91 – Dermatopolymyositis, unspecified with respiratory involvement
- M33.92 – Dermatopolymyositis, unspecified myopathy
- M33.93 – Dermatopolymyositis, unspecified without myopathy
- M33.99 – Dermatopolymyositis, unspecified with other organ involvement
- G72.41 – Other and unspecified myopathies
- G72.0 – Drug-induced myopathy
- G72.2 – Myopathy due to other toxic agents
- G72.41 – Inflammatory and immune myopathies, not elsewhere
- G72.49 – Other inflammatory and immune myopathies, not elsewhere classified
- G72.8 – Other specified myopathies
- G72.9 – Myopathy, unspecified
- G73.7 – Myopathy in diseases classified elsewhere
- M36.0 – Dermato(poly)myositis in neoplastic disease
- I42.7 – Cardiomyopathy due to drug and external agent
- I42.9 – Cardiomyopathy, unspecified
- I43 – Cardiomyopathy in diseases classified elsewhere
- I42 – Cardiomyopathy
- M79.1 – Myalgia
- M79.7 – Fibromyalgia
- I42.5 – Other restrictive cardiomyopathy
- I42.8 – Other cardiomyopathies

- Immune thrombocytopenia*
  - D69.3 – Immune thrombocytopenic purpura
- Kawasaki disease*
  - M30.3 – Mucocutaneous lymph node syndrome [Kawasaki]
- Multi inflammatory syndrome (in children and adults)*
  - U07.1 – COVID-19 **and one of the following:**
  - M35.8 – Other specified systemic involvement of connective tissue

  - M35.81 – Multisystem inflammatory syndrome
  - M35.89 – Other specified systemic involvement of connective tissue
- Multiple sclerosis
  - G35 – Multiple sclerosis
- Myocardial infarction*
  - I21.01 – ST elevation (STEMI) myocardial infarction involving left main coronary artery
  - I21.02 – ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
  - I21.09 – ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
  - I21.11 – ST elevation (STEMI) myocardial infarction involving right coronary artery
  - I21.19 – ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
  - I21.21 – ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
  - I21.29 – ST elevation (STEMI) myocardial infarction involving other sites
  - I21.3 – ST elevation (STEMI) myocardial infarction of unspecified site
  - I21.4 – Non-ST elevation (NSTEMI) myocardial infarction
  - I21.9 – Acute myocardial infarction, unspecified
  - I21.A1 – Myocardial infarction type 2
  - I21.A9 – Other myocardial infarction type
  - I22.0 – Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
  - I22.1 – Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
  - I22.2 – Subsequent non-ST elevation (NSTEMI) myocardial infarction
  - I22.8 – Subsequent ST elevation (STEMI) myocardial infarction of other sites
  - I22.9 – Subsequent ST elevation (STEMI) myocardial infarction of unspecified site

- Myocarditis/pericarditis*
    - B33.22 – Viral myocarditis
    - B33.23 – Viral pericarditis
    - I30.0 – Acute nonspecific idiopathic pericarditis
    - I30.1 – Infective pericarditis
    - I30.8 – Other forms of acute pericarditis
    - I30.9 – Acute pericarditis, unspecified
    - I32 – Pericarditis in diseases classified elsewhere
    - I41 – Myocarditis in diseases classified elsewhere
    - I40.0 – Infective myocarditis
    - I40.1 – Isolated myocarditis
    - I40.8 – Other acute myocarditis
    - I40.9 – Acute myocarditis, unspecified
    - I51.4 – Myocarditis, unspecified
- Pulmonary embolism*
    - I26.02 – Saddle embolus of pulmonary artery with acute cor pulmonale
    - I26.09 – Other pulmonary embolism with acute cor pulmonale
    - I26.92 – Saddle embolus of pulmonary artery without acute cor pulmonale
    - I26.93 – Single subsegmental pulmonary embolism without acute cor pulmonale
    - I26.94 – Multiple subsegmental pulmonary emboli without acute cor pulmonale
    - I26.99 – Other pulmonary embolism without acute cor pulmonale
- Stroke, hemorrhagic*
    - I61.0 – Nontraumatic intracerebral hemorrhage in hemisphere, subcortical
    - I61.1 – Nontraumatic intracerebral hemorrhage in hemisphere, cortical
    - I61.2 – Nontraumatic intracerebral hemorrhage in hemisphere, unspecified
    - I61.3 – Nontraumatic intracerebral hemorrhage in brain stem
    - I61.4 – Nontraumatic intracerebral hemorrhage in cerebellum
    - I61.5 – Nontraumatic intracerebral hemorrhage, intraventricular
    - I61.6 – Nontraumatic intracerebral hemorrhage, multiple localized
    - I61.8 – Other nontraumatic intracerebral hemorrhage

  - I61.9 – Nontraumatic intracerebral hemorrhage, unspecified
  - I62.00 – Nontraumatic subdural hemorrhage, unspecified
  - I62.01 – Nontraumatic acute subdural hemorrhage
  - I62.02 – Nontraumatic subacute subdural hemorrhage
  - I62.9 – Nontraumatic intracranial hemorrhage, unspecified
- Stroke, ischemic*
  - I63.00 – Cerebral infarction due to thrombosis of unspecified precerebral artery
  - I63.011 – Cerebral infarction due to thrombosis of right vertebral artery
  - I63.012 – Cerebral infarction due to thrombosis of left vertebral artery
  - I63.013 – Cerebral infarction due to thrombosis of bilateral vertebral arteries
  - I63.019 – Cerebral infarction due to thrombosis of unspecified vertebral artery
  - I63.02 – Cerebral infarction due to thrombosis of basilar artery
  - I63.031 – Cerebral infarction due to thrombosis of right carotid artery
  - I63.032 – Cerebral infarction due to thrombosis of left carotid artery
  - I63.033 – Cerebral infarction due to thrombosis of bilateral carotid arteries
  - I63.039 – Cerebral infarction due to thrombosis of unspecified carotid artery
  - I63.09 – Cerebral infarction due to thrombosis of other precerebral artery
  - I63.10 – Cerebral infarction due to embolism of unspecified precerebral artery
  - I63.111 – Cerebral infarction due to embolism of right vertebral artery
  - I63.112 – Cerebral infarction due to embolism of left vertebral artery
  - I63.113 – Cerebral infarction due to embolism of bilateral vertebral arteries
  - I63.119 – Cerebral infarction due to embolism of unspecified vertebral artery
  - I63.12 – Cerebral infarction due to embolism of basilar artery
  - I63.131 – Cerebral infarction due to embolism of right carotid artery
  - I63.132 – Cerebral infarction due to embolism of left carotid artery
  - I63.133 – Cerebral infarction due to embolism of bilateral carotid arteries
  - I63.139 – Cerebral infarction due to embolism of unspecified carotid artery
  - I63.19 – Cerebral infarction due to embolism of other precerebral artery
  - I63.20 – Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
  - I63.211 – Cerebral infarction due to unspecified occlusion or stenosis of right vertebral arteries

- I63.212 – Cerebral infarction due to unspecified occlusion or stenosis of left vertebral arteries
- I63.213 – Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
- I63.219 – Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries
- I63.22 – Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries
- I63.231 – Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
- I63.232 – Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
- I63.233 – Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
- I63.239 – Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries
- I63.29 – Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
- I63.30 – Cerebral infarction due to thrombosis of unspecified cerebral artery
- I63.311 – Cerebral infarction due to thrombosis of right middle cerebral artery
- I63.312 – Cerebral infarction due to thrombosis of left middle cerebral artery
- I63.313 – Cerebral infarction due to thrombosis of bilateral middle cerebral arteries
- I63.319 – Cerebral infarction due to thrombosis of unspecified middle cerebral artery
- I63.321 – Cerebral infarction due to thrombosis of right anterior cerebral artery
- I63.322 – Cerebral infarction due to thrombosis of left anterior cerebral artery
- I63.323 – Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries
- I63.329 – Cerebral infarction due to thrombosis of unspecified anterior cerebral artery
- I63.331 – Cerebral infarction due to thrombosis of right posterior cerebral artery
- I63.332 – Cerebral infarction due to thrombosis of left posterior cerebral artery

- I63.333 – Cerebral infarction due to thrombosis of bilateral posterior cerebral arteries
- I63.339 – Cerebral infarction due to thrombosis of unspecified posterior cerebral artery
- I63.341 – Cerebral infarction due to thrombosis of right cerebellar artery
- I63.342 – Cerebral infarction due to thrombosis of left cerebellar artery
- I63.343 – Cerebral infarction due to thrombosis of bilateral cerebellar artery
- I63.349 – Cerebral infarction due to thrombosis of unspecified cerebellar artery
- I63.39 – Cerebral infarction due to thrombosis of other cerebral artery
- I63.40 – Cerebral infarction due to embolism of unspecified cerebral artery
- I63.411 – Cerebral infarction due to embolism of right middle cerebral artery
- I63.412 – Cerebral infarction due to embolism of left middle cerebral artery
- I63.413 – Cerebral infarction due to embolism of bilateral middle cerebral artery
- I63.419 – Cerebral infarction due to embolism of unspecified middle cerebral arteries
- I63.421 – Cerebral infarction due to embolism of right anterior cerebral artery
- I63.422 – Cerebral infarction due to embolism of left anterior cerebral artery
- I63.423 – Cerebral infarction due to embolism of bilateral anterior cerebral arteries
- I63.429 – Cerebral infarction due to embolism of unspecified anterior cerebral artery
- I63.431 – Cerebral infarction due to embolism of right posterior cerebral artery
- I63.432 – Cerebral infarction due to embolism of left posterior cerebral artery
- I63.433 – Cerebral infarction due to embolism of bilateral anterior cerebral arteries
- I63.439 – Cerebral infarction due to embolism of unspecified posterior cerebral artery
- I63.441 – Cerebral infarction due to embolism of right cerebellar artery
- I63.442 – Cerebral infarction due to embolism of left cerebellar artery
- I63.443 – Cerebral infarction due to embolism of bilateral cerebellar arteries
- I63.449 – Cerebral infarction due to embolism of unspecified cerebellar artery
- I63.49 – Cerebral infarction due to embolism of other cerebellar artery

- I63.50 – Cerebral infarction due to embolism of unspecified cerebral artery
- I63.511 – Cerebral infarction due to embolism of right middle cerebral artery
- I63.512 – Cerebral infarction due to embolism of left middle cerebral artery
- I63.513 – Cerebral infarction due to embolism of bilateral middle cerebral arteries
- I63.519 – Cerebral infarction due to embolism of unspecified middle cerebral artery
- I63.521 – Cerebral infarction due to embolism of right anterior cerebral artery
- I63.522 – Cerebral infarction due to embolism of left anterior cerebral artery
- I63.523 – Cerebral infarction due to embolism of bilateral anterior cerebral artery
- I63.529 – Cerebral infarction due to embolism of unspecified anterior cerebral artery
- I63.531 – Cerebral infarction due to embolism of right posterior cerebral artery
- I63.532 – Cerebral infarction due to embolism of left posterior cerebral artery
- I63.533 – Cerebral infarction due to embolism of bilateral posterior cerebral arteries
- I63.539 – Cerebral infarction due to embolism of unspecified posterior cerebral artery
- I63.541 – Cerebral infarction due to embolism of right cerebellar artery
- I63.542 – Cerebral infarction due to embolism of left cerebellar artery
- I63.543 – Cerebral infarction due to embolism of bilateral cerebellar arteries
- I63.549 – Cerebral infarction due to embolism of unspecified cerebellar artery
- I63.59 – Cerebral infarction due to embolism of other cerebellar artery
- I63.6 – Cerebral infarction dye to cerebral venous thrombosis, nonpyogenic
- I63.81 – Other cerebral infarction due to occlusion or stenosis of small artery
- I63.89 – Other cerebral infarction
- I63.9 – Cerebral infarction, unspecified

- Transverse myelitis*
    - G37.3 – Acute transverse myelitis in demyelinating disease of central nervous system

In Phase 2 of the study, the following pregnancy outcomes will be assessed in pregnant women or their infants, if sample size permits:

- Spontaneous abortion (Chomistek et al., 2023)
    - O02.1 – Missed abortion
    - O03.** Spontaneous abortion
    - O03.0 – Genital tract and pelvic infection following incomplete spontaneous abortion
    - O03.1 – Delayed or excessive hemorrhage following incomplete spontaneous abortion
    - O03.2 – Embolism following incomplete spontaneous abortion
    - O03.30 – Unspecified complication following incomplete spontaneous abortion
    - O03.31 – Shock following incomplete spontaneous abortion
    - O03.32 – Renal failure following incomplete spontaneous abortion
    - O03.33 – Metabolic disorder following incomplete spontaneous abortion
    - O03.34 – Damage to pelvic organs following incomplete spontaneous abortion
    - O03.35 – Other venous complications following incomplete spontaneous abortion
    - O03.36 – Cardiac arrest following incomplete spontaneous abortion
    - O03.37 – Sepsis following incomplete spontaneous abortion
    - O03.38 – Urinary tract infection following incomplete spontaneous abortion
    - O03.39 – Incomplete spontaneous abortion with other complications
    - O03.4 – Incomplete spontaneous abortion without complication
    - O03.5 – Genital tract and pelvic infection following complete or unspecified spontaneous abortion
    - O03.6 – Delayed or excessive hemorrhage following complete or unspecified spontaneous abortion
    - O03.7 – Embolism following complete or unspecified spontaneous abortion
    - O03.80 – Unspecified complication following complete or unspecified spontaneous abortion

- O03.81 – Shock following complete or unspecified spontaneous abortion
- O03.82 – Renal failure following complete or unspecified spontaneous abortion
- O03.83 – Metabolic disorder following complete or unspecified spontaneous abortion
- O03.84 – Damage to pelvic organs following complete or unspecified spontaneous abortion
- O03.85 – Other venous complications following complete or unspecified spontaneous abortion
- O03.86 – Cardiac arrest following complete or unspecified spontaneous abortion
- O03.87 – Sepsis following complete or unspecified spontaneous abortion
- O03.88 – Urinary tract infection following complete or unspecified spontaneous abortion
- O03.89 – Complete or unspecified spontaneous abortion with other complications
- O03.9 – Complete or unspecified spontaneous abortion without complication
- O31.1 – Continuing pregnancy after spontaneous abortion of one fetus or more
- O31.2 – Continuing pregnancy after intrauterine death of one fetus or more
- O36.4 – Maternal care for intrauterine death
- CPT[8] 59800 – Treatment of spontaneous abortion, first trimester
- CPT 59801 – Treatment of spontaneous abortion, first trimester
- CPT 59810 – Treatment of spontaneous abortion, second trimester
- CPT 59811 – Treatment of spontaneous abortion, second trimester

- Stillbirth
  - O31.2 – Continuing pregnancy after intrauterine death of one fetus or more
  - O36.4 – Maternal care for intrauterine death
  - P95 – Stillbirth
  - Z37.1 – Single stillbirth
  - Z37.3 – Twins, one liveborn and one stillborn
  - Z37.4 – Twins, both stillborn

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  - Z37.60 – Multiple births, unspecified, some liveborn
  - Z37.61 – Triplets, some liveborn
  - Z37.62 – Quadruplets, some liveborn
  - Z37.63 – Quintuplets, some liveborn
  - Z37.64 – Sextuplets, some liveborn
  - Z37.69 – Other multiple births, some liveborn
  - Z37.7 – Other multiple births, all stillborn
- Preterm birth
  - O60.1 – Preterm labor with preterm delivery
  - P07.2 – Extreme immaturity of newborn
  - P07.3 – Preterm [premature] newborn [other]
  - P07.30 – Preterm newborn, unspecified weeks of gestation
  - P07.31 – Preterm newborn, gestational age 28 completed weeks
  - P07.32 – Preterm newborn, gestational age 29 completed weeks
  - P07.33 – Preterm newborn, gestational age 30 completed weeks
  - P07.34 – Preterm newborn, gestational age 31 completed weeks
  - P07.35 – Preterm newborn, gestational age 32 completed weeks
  - P07.36 – Preterm newborn, gestational age 33 completed weeks
  - P07.37 – Preterm newborn, gestational age 34 completed weeks
  - P07.38 – Preterm newborn, gestational age 35 completed weeks
  - P07.39 – Preterm newborn, gestational age 36 completed weeks
- Small for gestational age
  - P05.10 to P05.19 – Newborn small for gestational age
- Major congenital malformations

The following list of congenital malformation subcategories and codes is based on the EUROCAT Guide 1.4 dated 28 December 2018 (EUROCAT, 2020) and the New York State Department of Health Congenital Malformations Registry coding manual dated 22 October 2019 (New York State Department of Health Birth Defects Registry, 2021), consistent with those tracked by the Metropolitan Atlanta Congenital Defects Program (CDC, 2023a).

EUROCAT subgroups	**ICD-10 code**
All anomalies	Q-chapter, D21.5, D82.1, P35.0, P35.1, P37.1
Nervous system	Q00*, Q01*, Q02, Q03, Q04*, Q05*, Q06*, Q07**
Neural tube defects	Q00*, Q01*, Q05*
Anencephaly and similar malformations	Q00*
Encephalocele	Q01*
Spina bifida	Q05*
Hydrocephalus	Q03
Microcephaly	Q02
Arhinencephaly/holoprosencephaly	Q04.1, Q04.2
Eye	Q10*, Q11*, Q12*, Q13**, Q14*, Q15*
Anophthalmos/microphthalmos	Q11.0, Q11.1, Q11.2
Anophthalmos	Q11.0, Q11.1
Congenital cataract	Q12.0
Congenital glaucoma	Q15.0
Ear, face, and neck	Q16*-Q18*
Anotia	Q16.0
Circulatory System	Q20*, Q21*, Q22*, Q23*, Q24*, Q25**, Q26*, Q27**, Q28*
Severe congenital heart defects	Q20.0, Q20.1, Q20.3, Q20.4, Q21.2, Q21.3, Q22.0, Q22.4, Q22.5, Q22.6, Q23.0, Q23.2, Q23.3, Q23.4, Q25.1, Q25.2*, Q26.2
Common arterial truncus	Q20.0
Double outlet right ventricle	Q20.1
Transposition of great vessels	Q20.3
Single ventricle	Q20.4
Ventricular septal defect (VSD)	Q21.0
Atrial septal defect (ASD)	Q21.1
Atrioventricular septal defect (AVSD)	Q21.2
Tetralogy of Fallot	Q21.3
Tricuspid atresia and stenosis	Q22.4
Ebstein's anomaly	Q22.5
Pulmonary valve stenosis	Q22.1
Pulmonary valve atresia	Q22.0
Aortic valve atresia/stenosis	Q23.0
Mitral valve anomalies	Q23.2, Q23.3
Hypoplastic left heart	Q23.4
Hypoplastic right heart	Q22.6
Coarctation of aorta	Q25.1
Aortic atresia / interrupted aortic arch	Q25.2*
Total anomalous pulmonary venous return (TAPVR)	Q26.2
Patent ductus arteriosus (PDA) as only congenital heart disease (CHD) in term infants (gestational age +37 weeks)	Q25.0

EUROCAT subgroups	ICD-10 code
Respiratory	Q30*-Q34*
Choanal atresia	Q30.0
Cystic adenomatoid malformation of lung	Q33.0
EUROCAT subgroups	**ICD-10 code**
Oro-facial clefts	Q35*-Q37*
Cleft lip with or without cleft palate	Q36*, Q37*
Cleft palate	Q35*
Digestive system	Q38*-Q45*, Q79.0
Esophageal atresia with or without trachea-esophageal fistula	Q39.0, Q39.1
Duodenal atresia or stenosis	Q41.0
Atresia or stenosis of other parts of small intestine	Q41.1, Q41.2, Q41.8
Ano-rectal atresia and stenosis	Q42.0-Q42.3
Hirschsprung's disease	Q43.1
Atresia of bile ducts	Q44.2
Annular pancreas	Q45.1
Diaphragmatic hernia	Q79.0
Abdominal wall defects	Q79.2, Q79.3, Q79.5*
Gastroschisis	Q79.3
Omphalocele	Q79.2
Urinary	Q60*, Q61**, Q62**, Q63*, Q64**, Q79.4
Bilateral renal agenesis including Potter syndrome	Q60.1, Q60.6
Multicystic renal dysplasia	Q61.4
Congenital hydronephrosis	Q62.0
Bladder exstrophy and/or epispadias	Q64.0, Q64.1*
Posterior urethral valve and/or prune belly	Q64.2, Q79.4
Genital	Q50**, Q51***, Q52***, Q54*, Q55**, Q56*
Hypospadias	Q54*
Indeterminate sex	Q56*
Musculoskeletal	Q65**, Q66***, Q67*, Q68*, Q69*, Q70**, Q71***, Q72***, Q73*, Q74*, Q75*, Q76***, Q77*, Q78*, Q79**
Limb reduction defects	Q71***, Q72***, Q73*
Club foot – talipes equinovarus	Q66.0*
Hip dislocation and/or dysplasia	Q65.0*, Q65.1, Q65.2, Q65.80, Q65.81
Polydactyly	Q69*
Syndactyly	Q70**
Other anomalies/syndromes	
Skeletal dysplasias	Q74.0, Q77*, Q78.0, Q78.2-Q78.8
Craniosynostosis	Q75.0
Congenital constriction bands/amniotic band	Q79.8
Situs inversus	Q89.3
Conjoined twins	Q89.4
Congenital skin disorders	Q80*-Q82*
VATER/VACTERL	Q87.2
Laterality anomalies	Q20.6, Q24.0, Q33.8, Q89.0, Q89.3
Teratogenic syndromes with malformations	Q86*, P35.0, P35.1, P37.1
Fetal alcohol syndrome	Q86.0
Valproate syndrome	Q86.8
Maternal infections resulting in malformations	P35.0, P35.1, P37.1

EUROCAT subgroups	ICD-10 code
Genetic syndromes and microdeletions	Q44.7, Q61.9, Q74.8, Q75.1, Q75.4, Q75.8, Q87**, Q93.51, D82.1

* Indicates how many additional decimal places may be included though not required in the wildcard, including the number listed. For instance, Q93
** should include the following: Q93 (non-billable), Q93.0, Q93.1, Q93.2, Q93.3, Q93.4, Q93.5 (non-billable), Q93.51, Q93.59, Q93.7, Q93.8 (non-billable), Q93.81, Q93.82, Q93.88, Q93.89, Q93.9.
Chromosomal disorders are not included in the outcomes of interest

17.4. Appendix IV – Covariate Codes

17.4.1. Comorbidities

17.4.1.1. Asthma

17.4.1.1.1. ICD-10-CM Codes

J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.991	Cough variant asthma
J45.998	Other asthma
J82.83	Eosinophilic asthma

17.4.1.2. Non-Malignant Blood Disorders

17.4.1.2.1. ICD-10-CM Codes

D55.0	Anemia due to G6PD deficiency
D55.1	Anemia due to other disorders of glutathione metabolism
D55.21	Anemia due to pyruvate kinase deficiency
D55.29	Anemia due to other disorders of glycolytic enzymes
D55.3	Anemia due to disorders of nucleotide metabolism
D55.8	Other anemias due to enzyme disorders
D55.9	Anemia due to enzyme disorder, unspecified
D56.0	Alpha thalassemia
D56.1	Beta thalassemia
D56.2	Delta-beta thalassemia
D56.3	Thalassemia minor
D56.4	Hereditary persistence of fetal hemoglobin [HPFH]
D56.5	Hemoglobin E-beta thalassemia
D56.8	Other thalassemias
D56.9	Thalassemia, unspecified
D57.00	Hb-SS disease w/ crisis, unspecified
D57.01	Hb-SS disease w/ acute chest syndrome
D57.02	Hb-SS disease w/ splenic sequestration
D57.03	Hb-SS disease with cerebral vascular involvement
D57.04	Hb-SS disease with dactylitis
D57.09	Hb-SS disease with crisis with other specified complication
D57.1	Sickle cell disease w/o crisis
D57.20	Sickle cell/Hb-C disease w/o crisis

D57.21	Sickle cell/Hb-C disease w/ crisis
D57.211	Sickle cell/Hb-C disease w/ acute chest syndrome
D57.212	Sickle cell/Hb-C disease w/ splenic sequestration
D57.213	Sickle-cell/Hb-C disease with cerebral vascular involvement
D57.214	Sickle-cell/Hb-C disease with dactylitis
D57.218	Sickle-cell/Hb-C disease with crisis with other specified complication
D57.219	Sickle cell/Hb-C disease w/ crisis, unspecified
D57.3	Sickle cell trait
D57.40	Sickle cell thalassemia w/o crisis
D57.41	Sickle-cell thalassemia w/ crisis
D57.411	Sickle cell thalassemia w/ acute chest syndrome
D57.412	Sickle cell thalassemia w/ splenic sequestration
D57.413	Sickle-cell thalassemia, unspecified, with cerebral vascular involvement
D57.414	Sickle-cell thalassemia, unspecified, with dactylitis
D57.418	Sickle-cell thalassemia, unspecified, with crisis with other specified complication
D57.419	Sickle cell thalassemia w/ crisis, unspecified
D57.42	Sickle-cell thalassemia beta zero without crisis
D57.431	Sickle-cell thalassemia beta zero with acute chest syndrome
D57.432	Sickle-cell thalassemia beta zero with splenic sequestration
D57.433	Sickle-cell thalassemia beta zero with cerebral vascular involvement
D57.434	Sickle-cell thalassemia beta zero with dactylitis
D57.438	Sickle-cell thalassemia beta zero with crisis with other specified complication

D57.439	Sickle-cell thalassemia beta zero with crisis, unspecified
D57.44	Sickle-cell thalassemia beta plus without crisis
D57.451	Sickle-cell thalassemia beta plus with acute chest syndrome
D57.452	Sickle-cell thalassemia beta plus with splenic sequestration
D57.454	Sickle-cell thalassemia beta plus with dactylitis
D57.458	Sickle-cell thalassemia beta plus with crisis with other specified complication
D57.459	Sickle-cell thalassemia beta plus with crisis, unspecified
D57.80	Other sickle cell disorders w/o crisis
D57.811	Other sickle cell disorders w/ acute chest syndrome
D57.812	Other sickle cell disorders w/ splenic sequestration
D57.813	Other sickle-cell disorders with cerebral vascular involvement
D57.814	Other sickle-cell disorders with dactylitis
D57.818	Other sickle-cell disorders with crisis with other specified complication
D57.819	Other sickle cell disorders w/ crisis, unspecified
D58.0	Hereditary spherocytosis
D58.1	Hereditary elliptocytosis
D58.2	Other hemoglobinopathies
D58.8	Other specified hereditary hemolytic anemias
D58.9	Hereditary hemolytic anemia, unspecified
D59.0	Drug-induced autoimmune hemolytic anemia
D59.10	Autoimmune hemolytic anemia, unspecified
D59.11	Warm autoimmune hemolytic anemia
D59.12	Cold autoimmune hemolytic anemia

D59.13	Mixed type autoimmune hemolytic anemia
D59.19	Other autoimmune hemolytic anemia
D59.2	Drug-induced nonautoimmune hemolytic anemia
D59.30	Hemolytic-uremic syndrome, unspecified
D59.31	Infection-associated hemolytic-uremic syndrome
D59.32	Hereditary hemolytic-uremic syndrome
D59.39	Other hemolytic-uremic syndrome
D59.4	Other nonautoimmune hemolytic anemias
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
D59.6	Hemoglobinuria due to hemolysis from other external causes
D59.8	Other acquired hemolytic anemias
D59.9	Acquired hemolytic anemia, unspecified
D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D60.9	Acquired pure red cell aplasia, unspecified
D61.01	Constitutional (pure) red blood cell aplasia
D61.02	Shwachman-Diamond syndrome
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia

D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D62	Acute posthemorrhagic anemia
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.0	Hereditary sideroblastic anemia
D64.1	Secondary sideroblastic anemia due to disease
D64.2	Secondary sideroblastic anemia due to drugs and toxins
D64.3	Other sideroblastic anemias
D64.4	Congenital dyserythropoietic anemia
D64.81	Anemia due to antineoplastic chemotherapy
D64.89	Other specified anemias
D64.9	Anemia, unspecified
D65	Disseminated intravascular coagulation
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency
D68.00	Von Willebrand disease, unspecified
D68.1	Hereditary factor XI deficiency
D68.01	Von Willebrand disease, type 1
D68.020	Von Willebrand disease, type 2A
D68.021	Von Willebrand disease, type 2B

D68.022	Von Willebrand disease, type 2M
D68.023	Von Willebrand disease, type 2N
D68.029	Von Willebrand disease, type 2, unspecified
D68.03	Von Willebrand disease, type 3
D68.04	Acquired von Willebrand disease
D68.09	Other von Willebrand disease
D68.1	Hereditary factor XI deficiency
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia
D68.312	Antiphospholipid antibody with hemorrhagic disorder
D68.318	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
D68.32	Hemorrhagic disorder due to extrinsic circulating anticoagulants
D68.4	Acquired coagulation factor deficiency
D68.51	Activated protein C resistance
D68.52	Prothrombin gene mutation
D68.59	Other primary thrombophilia
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome
D68.69	Other thrombophilia
D68.8	Other specified coagulation defects
D68.9	Coagulation defect, unspecified
D69.0	Allergic purpura
D69.1	Qualitative platelet defects

D69.2	Other nonthrombocytopenic purpura
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
D69.42	Congenital and hereditary thrombocytopenia purpura
D69.49	Other primary thrombocytopenia
D69.51	Post-transfusion purpura
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified,
D71	Functional disorders of polymorphonuclear neutrophils
D72.0	Genetic anomalies of leukocytes
D72.10	Eosinophilia, unspecified
D72.110	Idiopathic hypereosinophilic syndrome [IHES]
D72.111	Lymphocytic Variant Hypereosinophilic Syndrome [LHES]
D72.118	Other hypereosinophilic syndrome
D72.119	Hypereosinophilic syndrome [HES], unspecified

D72.12	Drug rash with eosinophilia and systemic symptoms syndrome
D72.18	Eosinophilia in diseases classified elsewhere
D72.19	Other eosinophilia
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.820	Lymphocytosis (symptomatic)
D72.821	Monocytosis (symptomatic)
D72.822	Plasmacytosis
D72.823	Leukemoid reaction
D72.824	Basophilia
D72.825	Bandemia
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified

17.4.1.3. Chronic Lung Disease

17.4.1.3.1. ICD-10-CM Codes

P27.0	Wilson-Mikity syndrome
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P27.9	Unspecified chronic respiratory disease originating in the perinatal period
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis

E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis, unspecified
I27.0	Primary pulmonary hypertension
I27.1	Kyphoscoliotic heart disease
I27.20	Pulmonary hypertension, unspecified
I27.21	Secondary pulmonary arterial hypertension
I27.22	Pulmonary hypertension due to left heart disease
I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I27.24	Chronic thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension
I27.81	Cor pulmonale (chronic)
I27.82	Chronic pulmonary embolism
I27.83	Eisenmenger's syndrome
I27.89	Other specified pulmonary heart diseases
I27.9	Pulmonary heart disease, unspecified
I28.0	Arteriovenous fistula of pulmonary vessels
I28.1	Aneurysm of pulmonary artery
I28.8	Other diseases of pulmonary vessels
I28.9	Disease of pulmonary vessels, unspecified
J41	Simple and mucopurulent chronic bronchitis
J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis

J42	Unspecified chronic bronchitis
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.81	Bronchiolitis obliterans and bronchiolitis obliterans syndrome
J44.89	Other specified chronic obstructive pulmonary disease
J44.9	Chronic obstructive pulmonary disease, unspecified
J60	Coal worker's pneumoconiosis
J61	Pneumoconiosis due to asbestos and other mineral fibers
J62.0	Pneumoconiosis due to talc dust
J62.8	Pneumoconiosis due to other dust containing silica
J63.0	Aluminosis (of lung)
J63.1	Bauxite fibrosis (of lung)
J63.2	Berylliosis
J63.3	Graphite fibrosis (of lung)
J63.4	Siderosis
J63.5	Stannosis
J63.6	Pneumoconiosis due to other specified inorganic dusts
J64	Unspecified pneumoconiosis
J65	Pneumoconiosis associated with tuberculosis

J66.0	Byssinosis
J66.1	Flax-dressers' disease
J66.2	Cannabinosis
J66.8	Airway disease due to other specific organic dusts
J67	Hypersensitivity pneumonitis due to organic dust
J67.0	Farmer’s lung
J67.1	Bagassosis
J67.2	Bird fancier's lung
J67.3	Suberosis
J67.4	Maltworker's lung
J67.5	Mushroom-worker's lung
J67.6	Maple-bark-stripper's lung
J67.7	Air conditioner and humidifier lung
J67.8	Hypersensitivity pneumonitis due to other organic dusts
J67.9	Hypersensitivity pneumonitis due to unspecified organic dust
J68.4	Chronic respiratory conditions due to chemicals, gases, fumes and vapors
J68.8	Other respiratory conditions due to chemicals, gases, fumes and vapors
J68.9	Unspecified respiratory condition due to chemicals, gases, fumes and vapors
J70.1	Chronic and other pulmonary manifestations due to radiation
J70.3	Chronic drug-induced interstitial lung disorders
J70.5	Respiratory conditions due to smoke inhalation
J81.1	Chronic pulmonary edema
J82.81	Chronic eosinophilic pneumonia

J84.01	Alveolar proteinosis
J84.02	Pulmonary alveolar microlithiasis
J84.03	Idiopathic pulmonary hemosiderosis
J84.09	Other alveolar and parieto-alveolar conditions
J84.10	Pulmonary fibrosis, unspecified
J84.111	Idiopathic interstitial pneumonia, not otherwise specified
J84.112	Idiopathic pulmonary fibrosis
J84.113	Idiopathic non-specific interstitial pneumonitis
J84.115	Respiratory bronchiolitis interstitial lung disease
J84.116	Cryptogenic organizing pneumonia
J84.117	Desquamative interstitial pneumonia
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
J84.2	Lymphoid interstitial pneumonia
J84.81	Lymphangioleiomyomatosis
J84.82	Adult pulmonary Langerhans cell histiocytosis
J84.83	Surfactant mutations of the lung
J84.841	Neuroendocrine cell hyperplasia of infancy
J84.842	Pulmonary interstitial glycogenosis
J84.843	Alveolar capillary dysplasia with vein misalignment
J84.848	Other interstitial lung diseases of childhood
J84.89	Other specified interstitial pulmonary diseases
J84.9	Interstitial pulmonary disease, unspecified

Z77.090 Contact with and (suspected) exposure to asbestos

J85.0 Gangrene and necrosis of lung

J93.81 Chronic pneumothorax

17.4.1.4. Down Syndrome

17.4.1.4.1. ICD-10-CM Codes

Q90.0 Trisomy 21, nonmosaicism (meiotic nondisjunction)

Q90.1 Trisomy 21, mosaicism (mitotic nondisjunction)

Q90.2 Trisomy 21, translocation

Q90.9 Down syndrome, unspecified

17.4.1.5. Heart Disease

17.4.1.5.1. ICD-10-CM Codes

I01.0 Acute rheumatic pericarditis

I01.1 Acute rheumatic endocarditis

I01.2 Acute rheumatic myocarditis

I01.8 Other acute rheumatic heart disease

I01.9 Acute rheumatic heart disease, unspecified

I02.0 Rheumatic chorea with heart involvement

I05.0 Rheumatic mitral stenosis

I05.1 Rheumatic mitral insufficiency

I05.2 Rheumatic mitral stenosis with insufficiency

I05.8 Other rheumatic mitral valve diseases

I05.9 Rheumatic mitral valve disease, unspecified

I06.0 Rheumatic aortic stenosis

I06.1 Rheumatic aortic insufficiency

I06.2 Rheumatic aortic stenosis with insufficiency

I07.0	Rheumatic tricuspid stenosis
I07.1	Rheumatic tricuspid insufficiency
I07.2	Rheumatic tricuspid stenosis and insufficiency
I07.8	Other rheumatic tricuspid valve diseases
I07.9	Rheumatic tricuspid valve disease, unspecified
I06.8	Other rheumatic aortic valve diseases
I06.9	Rheumatic aortic valve disease, unspecified
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.1	Rheumatic disorders of both mitral and tricuspid valves
I08.2	Rheumatic disorders of both aortic and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I08.8	Other rheumatic multiple valve diseases
I08.9	Rheumatic multiple valve disease, unspecified
I09.0	Rheumatic myocarditis
I09.1	Rheumatic diseases of endocardium, valve unspecified
I09.2	Chronic rheumatic pericarditis
I09.81	Rheumatic heart failure
I09.89	Other specified rheumatic heart diseases
I09.9	Rheumatic heart disease, unspecified
I11.0	Hypertensive heart disease with heart failure
I11.9	Hypertensive heart disease without heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease

I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I20.0	Unstable angina
I20.1	Angina pectoris with documented spasm
I20.8	Other forms of angina pectoris
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I21.9	Acute myocardial infarction, unspecified
I21.A1	Myocardial infarction type 2
I21.A9	Other myocardial infarction type
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall

I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I23.0	Hemopericardium as current complication following acute myocardial infarction
I23.1	Atrial septal defect as current complication following acute myocardial infarction
I23.2	Ventricular septal defect as current complication following acute myocardial infarction
I23.3	Rupture of cardiac wall without hemopericardium as current complication following acute myocardial infarction
I23.4	Rupture of chordae tendineae as current complication following acute myocardial infarction
I23.5	Rupture of papillary muscle as current complication following acute myocardial infarction
I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction
I23.7	Postinfarction angina
I23.8	Other current complications following acute myocardial infarction
I24.0	Acute coronary thrombosis not resulting in myocardial infarction
I24.1	Dressler's syndrome
I24.8	Other forms of acute ischemic heart disease
I24.9	Acute ischemic heart disease, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris

I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.3	Aneurysm of heart
I25.41	Coronary artery aneurysm
I25.42	Coronary artery dissection
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm

I25.728 Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris

I25.729 Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris

I25.730 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris

I25.731 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm

I25.738 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris

I25.739 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris

I25.750 Atherosclerosis of native coronary artery of transplanted heart with unstable angina

I25.751 Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm

I25.758 Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris

I25.759 Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris

I25.760 Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina

I25.761 Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm

I25.768 Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris

I25.769 Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris

I25.790 Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris

I25.791 Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm

I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83	Coronary atherosclerosis due to lipid rich plaque
I25.84	Coronary atherosclerosis due to calcified coronary lesion
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I27.1	Kyphoscoliotic heart disease
I27.22	Pulmonary hypertension due to left heart disease
I27.81	Cor pulmonale (chronic)
I27.83	Eisenmenger's syndrome
I27.9	Pulmonary heart disease, unspecified
I30.0	Acute nonspecific idiopathic pericarditis
I30.1	Infective pericarditis
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified

I31.0	Chronic adhesive pericarditis
I31.1	Chronic constrictive pericarditis
I31.2	Hemopericardium, not elsewhere classified
I31.3	Pericardial effusion (noninflammatory)
I31.4	Cardiac tamponade
I31.8	Other specified diseases of pericardium
I31.9	Disease of pericardium, unspecified
I33.0	Acute and subacute infective endocarditis
I33.9	Acute and subacute endocarditis, unspecified
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.8	Other nonrheumatic mitral valve disorders
I34.9	Nonrheumatic mitral valve disorder, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8	Other nonrheumatic aortic valve disorders
I35.9	Nonrheumatic aortic valve disorder, unspecified
I36.0	Nonrheumatic tricuspid (valve) stenosis
I36.1	Nonrheumatic tricuspid (valve) insufficiency
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I36.8	Other nonrheumatic tricuspid valve disorders
I36.9	Nonrheumatic tricuspid valve disorder, unspecified

I37.0	Nonrheumatic pulmonary valve stenosis
I37.1	Nonrheumatic pulmonary valve insufficiency
I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
I37.8	Other nonrheumatic pulmonary valve disorders
I37.9	Nonrheumatic pulmonary valve disorder, unspecified
I38	Endocarditis, valve unspecified
I39	Endocarditis and heart valve disorders in diseases classified elsewhere
I40.0	Infective myocarditis
I40.1	Isolated myocarditis
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
I41	Myocarditis in diseases classified elsewhere
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I44.0	Atrioventricular block, first degree

I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I44.3	Other and unspecified atrioventricular block
I44.30	Unspecified atrioventricular block
I44.39	Other atrioventricular block
I44.4	Left anterior fascicular block
I44.5	Left posterior fascicular block
I44.60	Unspecified fascicular block
I44.69	Other fascicular block
I44.7	Left bundle-branch block, unspecified
I45.0	Right fascicular block
I45.10	Unspecified right bundle-branch block
I45.19	Other right bundle-branch block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.5	Other specified heart block
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I45.9	Conduction disorder, unspecified
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified

I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.20	Chronic atrial fibrillation, unspecified
I48.21	Permanent atrial fibrillation
I48.3	Typical atrial flutter
I48.4	Atypical atrial flutter
I48.91	Unspecified atrial fibrillation
I48.92	Unspecified atrial flutter
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome
I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure, unspecified

I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I51.0	Cardiac septal defect, acquired

I51.1 Rupture of chordae tendineae, not elsewhere classified

I51.2 Rupture of papillary muscle, not elsewhere classified

I51.3 Intracardiac thrombosis, not elsewhere classified

I51.4 Myocarditis, unspecified

I51.5 Myocardial degeneration

I51.7 Cardiomegaly

I51.81 Takotsubo syndrome

I51.89 Other ill-defined heart diseases

I51.9 Heart disease, unspecified

I52 Other heart disorders in diseases classified elsewhere

17.4.1.6. History of COVID-19

17.4.1.6.1. ICD-10-CM Codes

U07.1 COVID-19, virus identified

B97.29 Other coronavirus as the cause of diseases classified elsewhere

J12.82 Pneumonia due to coronavirus disease 2019

Z86.16 Personal history of COVID-19

17.4.1.7. Immunocompromised Status

17.4.1.7.1. ICD-10-CM Codes

D80.0 Hereditary hypogammaglobulinemia

D80.1 Nonfamilial hypogammaglobulinemia

D80.2 Selective deficiency of immunoglobulin A [IgA]

D80.3 Selective deficiency of immunoglobulin G [IgG] subclasses

D80.4 Selective deficiency of immunoglobulin M [IgM]

D80.5 Immunodeficiency with increased immunoglobulin M [IgM]

D80.6 Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia

D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.30	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency
D81.4	Nezelof's syndrome
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.8	Other combined immunodeficiencies
D81.81	Biotin-dependent carboxylase deficiency
D81.810	Biotinidase deficiency
D81.818	Other biotin-dependent carboxylase deficiency
D81.819	Biotin-dependent carboxylase deficiency, unspecified
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome

D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified
D83	Common variable immunodeficiency
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D84.9	Immunodeficiency, unspecified
B20	Human immunodeficiency virus [HIV] disease
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
O98.7	Human immunodeficiency virus [HIV] disease complicating pregnancy, childbirth and the puerperium
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
Z94.0	Kidney transplant status
Z94.1	Heart transplant status

Z94.2 Lung transplant status

Z94.3 Heart and lungs transplant status

Z94.4 Liver transplant status

Z94.5 Skin transplant status

Z94.6 Bone transplant status

Z94.7 Corneal transplant status

Z94.81 Bone marrow transplant status

Z94.82 Intestine transplant status

Z94.83 Pancreas transplant status

Z94.84 Stem cells transplant status

Z94.89 Other transplanted organ and tissue status

Z94.9 Transplanted organ and tissue status, unspecified

17.4.1.7.2. CPT Codes[9]

33935 Heart-lung transplant with recipient cardiectomy-pneumonectomy

33945 Heart transplant, with or without recipient cardiectomy

80158 Cyclosporine

80197 Tacrolimus

80195 Sirolimus

80180 Mycophenolate (mycophenolic acid)

17.4.1.7.3. HCPCS Codes

J0485 Injection, belatacept, 1 mg

J7500 Azathioprine, oral, 50 mg

J7501 Azathioprine, parenteral, 100 mg

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J7502	Cyclosporine, oral, 100 mg
J7503	Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg
J7504	Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg
J7505	Muromonab-CD3, parenteral, 5 mg
J7507	Tacrolimus, immediate release, oral, 1 mg
J7508	Tacrolimus, extended release, (Astagraf XL), oral, 0.1 mg
J7509	Methylprednisolone oral, per 4 mg
J7510	Prednisolone oral, per 5 mg
J7511	Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg
J7512	Prednisone, immediate release or delayed release, oral, 1 mg
J7513	Daclizumab, parenteral, 25 mg
J7515	Cyclosporine, oral, 25 mg
J7516	Cyclosporin, parenteral, 250 mg
J7517	Mycophenolate mofetil, oral, 250 mg
J7518	Mycophenolic acid, oral, 180 mg
J7519	Injection, mycophenolate mofetil, 10 mg
J7520	Sirolimus, oral, 1 mg
J7525	Tacrolimus, parenteral, 5 mg
J7527	Everolimus, oral, 0.25 mg
J7599	Immunosuppressive drug, not otherwise classified
J8530	Cyclophosphamide; oral, 25 mg
J8610	Methotrexate; oral, 2.5 mg

17.4.1.7.4. NDC Codes

NDC codes corresponding to the above immunosuppressant medications will be utilized where applicable.

17.4.1.8. Kidney Disorders

17.4.1.8.1. ICD-10-CM Codes

N00.0	Acute nephritic syndrome with minor glomerular abnormality
N00.1	Acute nephritic syndrome with focal and segmental glomerular lesions
N00.2	Acute nephritic syndrome with diffuse membranous glomerulonephritis
N00.3	Acute nephritic syndrome with diffuse mesangial proliferative glomerulonephritis
N00.4	Acute nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis
N00.5	Acute nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N00.6	Acute nephritic syndrome with dense deposit disease
N00.7	Acute nephritic syndrome with diffuse crescentic glomerulonephritis
N00.8	Acute nephritic syndrome with other morphologic changes
N00.9	Acute nephritic syndrome with unspecified morphologic changes
N01.0	Rapidly progressive nephritic syndrome with minor glomerular abnormality
N01.1	Rapidly progressive nephritic syndrome with focal and segmental glomerular lesions
N01.2	Rapidly progressive nephritic syndrome with diffuse membranous glomerulonephritis
N01.3	Rapidly progressive nephritic syndrome with diffuse mesangial proliferative glomerulonephritis
N01.4	Rapidly progressive nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis

N01.5 Rapidly progressive nephritic syndrome with diffuse mesangiocapillary glomerulonephritis

N01.6 Rapidly progressive nephritic syndrome with dense deposit disease

N01.7 Rapidly progressive nephritic syndrome with diffuse crescentic glomerulonephritis

N01.8 Rapidly progressive nephritic syndrome with other morphologic changes

N01.9 Rapidly progressive nephritic syndrome with unspecified morphologic changes

N02.0 Recurrent and persistent hematuria with minor glomerular abnormality

N02.1 Recurrent and persistent hematuria with focal and segmental glomerular lesions

N02.2 Recurrent and persistent hematuria with diffuse membranous glomerulonephritis

N02.3 Recurrent and persistent hematuria with diffuse mesangial proliferative glomerulonephritis

N02.4 Recurrent and persistent hematuria with diffuse endocapillary proliferative glomerulonephritis

N02.5 Recurrent and persistent hematuria with diffuse mesangiocapillary glomerulonephritis

N02.6 Recurrent and persistent hematuria with dense deposit disease

N02.7 Recurrent and persistent hematuria with diffuse crescentic glomerulonephritis

N02.8 Recurrent and persistent hematuria with other morphologic changes

N02.9 Recurrent and persistent hematuria with unspecified morphologic changes

N03.0 Chronic nephritic syndrome with minor glomerular abnormality

N03.1 Chronic nephritic syndrome with focal and segmental glomerular lesions

N03.2 Chronic nephritic syndrome with diffuse membranous glomerulonephritis

N03.3	Chronic nephritic syndrome with diffuse mesangial proliferative glomerulonephritis
N03.4	Chronic nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis
N03.5	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N03.6	Chronic nephritic syndrome with dense deposit disease
N03.7	Chronic nephritic syndrome with diffuse crescentic glomerulonephritis
N03.8	Chronic nephritic syndrome with other morphologic changes
N03.9	Chronic nephritic syndrome with unspecified morphologic changes
N04.0	Nephrotic syndrome with minor glomerular abnormality
N04.1	Nephrotic syndrome with focal and segmental glomerular lesions
N04.2	Nephrotic syndrome with diffuse membranous glomerulonephritis
N04.3	Nephrotic syndrome with diffuse mesangial proliferative glomerulonephritis
N04.4	Nephrotic syndrome with diffuse endocapillary proliferative glomerulonephritis
N04.5	Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis
N04.6	Nephrotic syndrome with dense deposit disease
N04.7	Nephrotic syndrome with diffuse crescentic glomerulonephritis
N04.8	Nephrotic syndrome with other morphologic changes
N04.9	Nephrotic syndrome with unspecified morphologic changes
N05.0	Unspecified nephritic syndrome with minor glomerular abnormality
N05.1	Unspecified nephritic syndrome with focal and segmental glomerular lesions
N05.2	Unspecified nephritic syndrome with diffuse membranous glomerulonephritis

N05.3	Unspecified nephritic syndrome with diffuse mesangial proliferative glomerulonephritis
N05.4	Unspecified nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis
N05.5	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N05.6	Unspecified nephritic syndrome with dense deposit disease
N05.7	Unspecified nephritic syndrome with diffuse crescentic glomerulonephritis
N05.8	Unspecified nephritic syndrome with other morphologic changes
N05.9	Unspecified nephritic syndrome with unspecified morphologic changes
N06.0	Isolated proteinuria with minor glomerular abnormality
N06.1	Isolated proteinuria with focal and segmental glomerular lesions
N06.2	Isolated proteinuria with diffuse membranous glomerulonephritis
N06.3	Isolated proteinuria with diffuse mesangial proliferative glomerulonephritis
N06.4	Isolated proteinuria with diffuse endocapillary proliferative glomerulonephritis
N06.5	Isolated proteinuria with diffuse mesangiocapillary glomerulonephritis
N06.6	Isolated proteinuria with dense deposit disease
N06.7	Isolated proteinuria with diffuse crescentic glomerulonephritis
N06.8	Isolated proteinuria with other morphologic lesion
N06.9	Isolated proteinuria with unspecified morphologic lesion
N07.0	Hereditary nephropathy, not elsewhere classified with minor glomerular abnormality
N07.1	Hereditary nephropathy, not elsewhere classified with focal and segmental glomerular lesions

N07.2	Hereditary nephropathy, not elsewhere classified with diffuse membranous glomerulonephritis
N07.3	Hereditary nephropathy, not elsewhere classified with diffuse mesangial proliferative glomerulonephritis
N07.4	Hereditary nephropathy, not elsewhere classified with diffuse endocapillary proliferative glomerulonephritis
N07.5	Hereditary nephropathy, not elsewhere classified with diffuse mesangiocapillary glomerulonephritis
N07.6	Hereditary nephropathy, not elsewhere classified with dense deposit disease
N07.7	Hereditary nephropathy, not elsewhere classified with diffuse crescentic glomerulonephritis
N07.8	Hereditary nephropathy, not elsewhere classified with other morphologic lesions
N07.9	Hereditary nephropathy, not elsewhere classified with unspecified morphologic lesions
N08	Glomerular disorders in diseases classified elsewhere
N10	Acute pyelonephritis
N11.0	Nonobstructive reflux-associated chronic pyelonephritis
N11.1	Chronic obstructive pyelonephritis
N11.8	Other chronic tubulo-interstitial nephritis
N11.9	Chronic tubulo-interstitial nephritis, unspecified
N12	Tubulo-interstitial nephritis, not specified as acute or chronic
N13.0	Hydronephrosis with ureteropelvic junction obstruction
N13.1	Hydronephrosis with ureteral stricture, not elsewhere classified
N13.2	Hydronephrosis with renal and ureteral calculous obstruction
N13.30	Unspecified hydronephrosis
N13.39	Other hydronephrosis

N13.4 Hydroureter

N13.5 Crossing vessel and stricture of ureter without hydronephrosis

N13.6 Pyonephrosis

N13.70 Vesicoureteral-reflux, unspecified

N13.71 Vesicoureteral-reflux without reflux nephropathy

N13.721 Vesicoureteral-reflux with reflux nephropathy without hydroureter, unilateral

N13.722 Vesicoureteral-reflux with reflux nephropathy without hydroureter, bilateral

N13.729 Vesicoureteral-reflux with reflux nephropathy without hydroureter, unspecified

N13.731 Vesicoureteral-reflux with reflux nephropathy with hydroureter, unilateral

N13.732 Vesicoureteral-reflux with reflux nephropathy with hydroureter, bilateral

N13.739 Vesicoureteral-reflux with reflux nephropathy with hydroureter, unspecified

N13.8 Other obstructive and reflux uropathy

N13.9 Obstructive and reflux uropathy, unspecified

N14.0 Analgesic nephropathy

N14.1 Nephropathy induced by other drugs, medicaments and biological substances

N14.2 Nephropathy induced by unspecified drug, medicament or biological substance

N14.3 Nephropathy induced by heavy metals

N14.4 Toxic nephropathy, not elsewhere classified

N15.0 Balkan nephropathy

N15.1 Renal and perinephric abscess

N15.8	Other specified renal tubulo-interstitial diseases
N15.9	Renal tubulo-interstitial disease, unspecified
N16	Renal tubulo-interstitial disorders in diseases classified elsewhere
N17.0	Acute kidney failure with tubular necrosis
N17.1	Acute kidney failure with acute cortical necrosis
N17.2	Acute kidney failure with medullary necrosis
N17.8	Other acute kidney failure
N17.9	Acute kidney failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified
N19	Unspecified kidney failure
N20.0	Calculus of kidney
N20.1	Calculus of ureter
N20.2	Calculus of kidney with calculus of ureter
N20.9	Urinary calculus, unspecified
N23	Unspecified renal colic
N25.0	Renal osteodystrophy
N25.1	Nephrogenic diabetes insipidus
N25.81	Secondary hyperparathyroidism of renal origin

N25.89	Other disorders resulting from impaired renal tubular function
N25.9	Disorder resulting from impaired renal tubular function, unspecified
N26	Unspecified contracted kidney
N26.1	Atrophy of kidney (terminal)
N26.2	Page kidney
N26.9	Renal sclerosis, unspecified
N27.0	Small kidney, unilateral
N27.1	Small kidney, bilateral
N27.9	Small kidney, unspecified
N28.0	Ischemia and infarction of kidney
N28.1	Cyst of kidney, acquired
N28.81	Hypertrophy of kidney
N28.82	Megaloureter
N28.83	Nephroptosis
N28.84	Pyelitis cystica
N28.85	Pyeloureteritis cystica
N28.86	Ureteritis cystica
N28.89	Other specified disorders of kidney and ureter
N28.9	Disorder of kidney and ureter, unspecified
N29	Other disorders of kidney and ureter in diseases classified elsewhere

17.4.1.9. Liver Disorders

17.4.1.9.1. ICD-10-CM Codes

K70.10	Alcoholic hepatitis without ascites
K70.11	Alcoholic hepatitis with ascites
K70.2	Alcoholic fibrosis and sclerosis of liver
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K70.40	Alcoholic hepatic failure without coma
K70.41	Alcoholic hepatic failure with coma
K70.9	Alcoholic liver disease, unspecified
K71.0	Toxic liver disease with cholestasis
K71.10	Toxic liver disease with hepatic necrosis, without coma
K71.11	Toxic liver disease with hepatic necrosis, with coma
K71.2	Toxic liver disease with acute hepatitis
K71.3	Toxic liver disease with chronic persistent hepatitis
K71.4	Toxic liver disease with chronic lobular hepatitis
K71.50	Toxic liver disease with chronic active hepatitis without ascites
K71.51	Toxic liver disease with chronic active hepatitis with ascites
K71.6	Toxic liver disease with hepatitis, not elsewhere classified
K71.7	Toxic liver disease with fibrosis and cirrhosis of liver
K71.8	Toxic liver disease with other disorders of liver
K71.9	Toxic liver disease, unspecified K72 Hepatic failure, not elsewhere classified Includes: fulminant hepatitis NEC, with hepatic failure
K72.00	Acute and subacute hepatic failure without coma
K72.01	Acute and subacute hepatic failure with coma

K72.10	Chronic hepatic failure without coma
K72.11	Chronic hepatic failure with coma
K72.90	Hepatic failure, unspecified without coma
K72.91	Hepatic failure, unspecified with coma
K73.0	Chronic persistent hepatitis, not elsewhere classified
K73.1	Chronic lobular hepatitis, not elsewhere classified
K73.2	Chronic active hepatitis, not elsewhere classified
K73.8	Other chronic hepatitis, not elsewhere classified
K73.9	Chronic hepatitis, unspecified
K74.0	Hepatic fibrosis
K74.1	Hepatic sclerosis
K74.2	Hepatic fibrosis with hepatic sclerosis
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.5	Biliary cirrhosis, unspecified
K74.60	Unspecified cirrhosis of liver
K74.69	Other cirrhosis of liver
K75.0	Abscess of liver
K75.1	Phlebitis of portal vein
K75.2	Nonspecific reactive hepatitis
K75.3	Granulomatous hepatitis, not elsewhere classified
K75.4	Autoimmune hepatitis
K75.81	Nonalcoholic steatohepatitis (NASH)
K75.89	Other specified inflammatory liver diseases

K75.9 Inflammatory liver disease, unspecified

K76.0 Fatty (change of) liver, not elsewhere classified

K76.1 Chronic passive congestion of liver

K76.2 Central hemorrhagic necrosis of liver

K76.3 Infarction of liver

K76.4 Peliosis hepatis

K76.5 Hepatic veno-occlusive disease

K76.6 Portal hypertension

K76.7 Hepatorenal syndrome

K76.81 Hepatopulmonary syndrome

K76.89 Other specified diseases of liver

K76.9 Liver disease, unspecified

K77 Liver disorders in diseases classified elsewhere

17.4.1.10. Neurological or Neurodevelopmental Conditions

17.4.1.10.1. ICD-10-CM Codes

F70 Mild intellectual disabilities

F71 Moderate intellectual disabilities

F72 Severe intellectual disabilities

F73 Profound intellectual disabilities

F78 Other intellectual disabilities

F79 Unspecified intellectual disabilities

F80.0 Phonological disorder

F80.1 Expressive language disorder

F80.2 Mixed receptive-expressive language disorder

F80.4 Speech and language development delay due to hearing loss

F80.81 Childhood onset fluency disorder

F80.82 Social pragmatic communication disorder

F80.89 Other developmental disorders of speech and language

F80.9 Developmental disorder of speech and language, unspecified

F81.0 Specific reading disorder

F81.2 Mathematics disorder

F81.81 Disorder of written expression

F81.89 Other developmental disorders of scholastic skills

F81.9 Developmental disorder of scholastic skills, unspecified

F82 Specific developmental disorder of motor function

F84.0 Autistic disorder

F84.2 Rett's syndrome

F84.3 Other childhood disintegrative disorder

F84.5 Asperger's syndrome

F84.8 Other pervasive developmental disorders

F84.9 Pervasive developmental disorder, unspecified

F89 Unspecified disorder of psychological development

17.4.1.11. Malignant Neoplasms

17.4.1.11.1. ICD-10-CM Codes

C00-C14 Malignant neoplasms of lip, oral cavity and pharynx

C15-C26 Malignant neoplasms of digestive organs

C30-C39 Malignant neoplasms of respiratory and intrathoracic organs

C40-C41 Malignant neoplasms of bone and articular cartilage

C43-C44 Melanoma and other malignant neoplasms of skin

C45-C49 Malignant neoplasms of mesothelial and soft tissue

C50	Malignant neoplasms of breast
C51-C58	Malignant neoplasms of female genital organs
C60-C63	Malignant neoplasms of male genital organs
C64-C68	Malignant neoplasms of urinary tract
C69-C72	Malignant neoplasms of eye, brain and other parts of central nervous system
C73-C75	Malignant neoplasms of thyroid and other endocrine glands
C7A	Malignant neuroendocrine tumors
C7B	Secondary neuroendocrine tumors
C76-C80	Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81-C96	Malignant neoplasms of lymphoid, hematopoietic and related tissue

17.4.1.12. Obesity

17.4.1.12.1. ICD-10-CM Codes

E66.0	Obesity due to excess calories
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.8	Other obesity
E66.9	Obesity, unspecified

17.4.1.13. Type 2 Diabetes

17.4.1.13.1. ICD-10-CM Codes

E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma

E11.11 Type 2 diabetes mellitus with ketoacidosis with coma

E11.21 Type 2 diabetes mellitus with diabetic nephropathy

E11.22 Type 2 diabetes mellitus with diabetic chronic kidney disease

E11.29 Type 2 diabetes mellitus with other diabetic kidney complication

E11.311 Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema

E11.319 Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema

E11.321 Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema

E11.329 Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema

E11.331 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema

E11.339 Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema

E11.341 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema

E11.349 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema

E11.351 Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema

E11.352 Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula

E11.353 Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula

E11.354 Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment

E11.355 Type 2 diabetes mellitus with stable proliferative diabetic retinopathy

E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma

E11.65 Type 2 diabetes mellitus with hyperglycemia

E11.69 Type 2 diabetes mellitus with other specified complication

E11.8 Type 2 diabetes mellitus with unspecified complications

E11.9 Type 2 diabetes mellitus without complications

17.4.2. Medication History

17.4.2.1. Systemic Immunomodulators

The below list includes generic drug names classified by therapeutic use. All associated NDC codes will be utilized. Additional therapies may be added as they are approved.

17.4.2.1.1. Immunomodulators

17.4.2.1.1.1. Colony-Stimulating Factors

ancestim
balugrastim
efbemalenograstim alfa
empegfilgrastim
filgrastim
lenograstim
lipegfilgrastim
molgramostim
pegfilgrastim
pegteograstim
sargramostim

17.4.2.1.1.2. Interferons

albinterferon alfa-2b
cepeginterferon alfa-2b
interferon alfa natural
interferon alfa-2a
interferon alfa-2b
interferon alfacon-1
interferon alfa-n1
interferon beta natural
interferon beta-1a
interferon beta-1b
interferon gamma
peginterferon alfa-2a
peginterferon alfa-2a, combinations
peginterferon alfa-2b

peginterferon alfa-2b, combinations
peginterferon alfacon-2
peginterferon beta-1a
ropeginterferon alfa-2b

17.4.2.1.1.3. Interleukins

aldesleukin
oprelvekin

17.4.2.1.1.4. Other Immunostimulants

BCG vaccine
cridanimod
dasiprotimut-T
elapegademase
glatiramer acetate
histamine dihydrochloride
immunocyanin
lentinan
melanoma vaccine
mifamurtide
pegademase
pidotimod
plerixafor
polyinosinic:polycytidylic acid (poly I:C)
poly ICLC
roquinimex
sipuleucel-T
tasonermin
thymopentin

17.4.2.1.2. Immunosuppresants

17.4.2.1.2.1. Selective Immunosuppressants

abatacept
abetimus
alefacept
alemtuzumab
anifrolumab
antilymphocyte immunoglobulin (horse)
antithymocyte immunoglobulin (rabbit)
apremilast
avacopan

baricitinib
begelomab
belatacept
belimumab
belumosudil
cladribine
deucravacitinib
eculizumab
efalizumab
efgartigimod alfa
emapalumab
everolimus
filgotinib
fingolimod
gusperimus
imlifidase
inebilizumab
itacitinib
leflunomide
muromonab-CD3
mycophenolic acid
natalizumab
ocrelizumab
ofatumumab
ozanimod
peficitinib
pegcetacoplan
ponesimod
ravulizumab
siponimod
sirolimus
sutimlimab
teprotumumab
teriflunomide
tofacitinib
ublituximab
upadacitinib
vedolizumab

17.4.2.1.2.2. Tumor Necrosis Factor Alpha (TNF-α) Inhibitors

adalimumab
afelimomab
certolizumab pegol
etanercept
golimumab
infliximab
opinercept

17.4.2.1.2.3. Interleukin Inhibitors

anakinra
basiliximab
bimekizumab
briakinumab
brodalumab
canakinumab
daclizumab
guselkumab
ixekizumab
netakimab
olokizumab
rilonacept
risankizumab
sarilumab
satralizumab
secukinumab
siltuximab
sirukumab
spesolimab
tildrakizumab
tocilizumab
ustekinumab

17.4.2.1.2.4. Calcineurin Inhibitors

cyclosporine
tacrolimus
voclosporin

17.4.2.1.2.5. Other Immunosuppresants

azathioprine
darvadstrocel
dimethyl fumarate
diroximel fumarate
lenalidomide
methotrexate
pirfenidone
pomalidomide
thalidomide

17.4.2.1.3. Chemotherapeutic Agents

17.4.2.1.3.1. Alkylating Agents

chlorambucil
cisplatin
cyclophosphamide

17.4.2.1.3.2. Antimetabolite Agents

5-fluorouracil
6-mercaptopurine
cytarabine
methotrexate

17.4.2.1.3.3. Antitumor Antibiotics

bleomycin
doxorubicin
mitomycin C

17.4.2.1.3.4. Mitotic Inhibitors

paclitaxel
plant alkaloids (vinblastine, vincristine)

17.4.2.1.3.5. Topoisomerase Inhibitors

etoposide
irinotecan
opotecan

17.4.2.1.4. Myelosuppresive Agents

hydroxyurea

17.4.2.1.5. ICD-10-CM, CPT[10] and HCPCS Codes

In addition to NDC codes for the above, the following ICD-10, CPT and HCPCS codes will be used:

ICD-10-CM:

T45.1***	Poisoning by, adverse effect of and underdosing of antineoplastic and immunosuppressive drugs
Z79.6	Long term (current) use of immunomodulators and immunosuppressants
Z79.60	Long term (current) use of unspecified immunomodulators and immunosuppressants
Z79.61	Long term (current) use of immunomodulator (apremilast, immunomodulatory imide drug, lenalidomide, pomalidomide)
Z79.62	Long term (current) use of immunosuppressant
Z79.620	Long term (current) use of immunosuppressive biologic (adalimumab, etanercept, infliximab, monoclonal antibodies)
Z79.621	Long term (current) use of calcineurin inhibitor (cyclosporine, tacrolimus)
Z79.622	Long term (current) use of Janus kinase inhibitor (tofacitinib)
Z79.623	Long term (current) use of mammalian target of rapamycin (mTOR) inhibitor (sirolimus)
Z79.624	Long term (current) use of inhibitors of nucleotide synthesis (azathioprine, omycophenolate, purine synthesis (IMDH) inhibitors)
Z79.63	Long term (current) use of chemotherapeutic agent
Z79.630	Long term (current) use of alkylating agent (chlorambucil, cisplatin, cyclophosphamide)
Z79.631	Long term (current) use of antimetabolite agent (5-fluorouracil, 6-mercaptopurine, cytarabine, methotrexate)

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Z79.632	Long term (current) use of antitumor antibiotic (bleomycin, doxorubicin, mitomycin C)
Z79.633	Long term (current) use of mitotic inhibitor (paclitaxel, plant alkaloids, vinblastine, vincristine)
Z79.634	Long term (current) use of topoisomerase inhibitor (etoposide, irinotecan, topotecan)
Z79.64	Long term (current) use of myelosuppressive agent (hydroxyurea)
Z79.69	Long term (current) use of other immunomodulators and immunosuppressants

ICD-10-PCS:

3E03302	Introduction of High-dose Interleukin-2 into Peripheral Vein, Percutaneous Approach
3E03303	Introduction of Low-dose Interleukin-2 into Peripheral Vein, Percutaneous Approach
3E04002	Introduction of High-dose Interleukin-2 into Central Vein, Open Approach
3E04003	Introduction of Low-dose Interleukin-2 into Central Vein, Open Approach
3E04302	Introduction of High-dose Interleukin-2 into Central Vein, Percutaneous Approach
3E04303	Introduction of Low-dose Interleukin-2 into Central Vein, Percutaneous Approach
3E05002	Introduction of High-dose Interleukin-2 into Peripheral Artery, Open Approach
3E05302	Introduction of High-dose Interleukin-2 into Peripheral Artery, Percutaneous Approach
3E050WK	Introduction of Immunostimulator into Peripheral Artery, Open
3E050WL	Introduction of Immunosuppressive into Peripheral Artery, Open

3E053WL	Introduction of Immunosuppressive into Peripheral Artery, Percutaneous
3E053WL	Introduction of Immunosuppressive into Peripheral Artery, Percutaneous
3E060WK	Introduction of Immunostimulator into Central Artery, Open
3E060WL	Introduction of Immunosuppressive into Central Artery, Open
3E063WK	Introduction of Immunostimulator into Central Artery, Percutaneous
3E063WL	Introduction of Immunosuppressive into Central Artery, Percutaneous
XW01397	Introduction of Satralizumab-mwge into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 7
XW033C6	Introduction of Eculizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 6
XW033H5	Introduction of Tocilizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW033L6	Introduction of CD24Fc Immunomodulator into Peripheral Vein, Percutaneous Approach, New Technology Group 6
XW033L7	Introduction of Lifileucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7
XW033M7	Introduction of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7
XW03308	Introduction of Spesolimab Monoclonal Antibody into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW03398	Introduction of Inebilizumab-cdon into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW04308	Introduction of Spesolimab Monoclonal Antibody into Central Vein, Percutaneous Approach, New Technology Group 8
XW04398	Introduction of Inebilizumab-cdon into Central Vein, Percutaneous Approach, New Technology Group 8

XW043G5	Introduction of Sarilumab into Central Vein, Percutaneous Approach, New Technology Group 5
XW043H5	Introduction of Tocilizumab into Central Vein, Percutaneous Approach, New Technology Group 5
XW043L6	Introduction of CD24Fc Immunomodulator into Central Vein, Percutaneous Approach, New Technology Group 6
XW0DXM6	Introduction of Baricitinib into Mouth and Pharynx, External Approach, New Technology Group 6
XW0G7M6	Introduction of Baricitinib into Upper GI, Via Natural or Artificial Opening, New Technology Group 6
XW0H7M6	Introduction of Baricitinib into Lower GI, Via Natural or Artificial Opening, New Technology Group 6

CPT[11]

80145	Adalimumab
80158	Cyclosporine
80169[12]	Everolimus
80180	Mycophenolate (mycophenolic acid)
80193	Leflunomide
80195	Sirolimus
80197	Tacrolimus
80180	Mycophenolate (mycophenolic acid)
80204	Methotrexate
80230	Infliximab
80280	Vedolizumab

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90585	Bacillus Calmette-Guerin vaccine (BCG) for tuberculosis, live, for percutaneous use
90586	Bacillus Calmette-Guerin vaccine (BCG) for bladder cancer, live, for intravesical use

HCPCS

J0129	Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J0135	Injection, adalimumab, 20 mg
S0176	Hydroxyurea, oral, 500 mg
J0215	Injection, alefacept, 0.5 mg
J0202	Injection, alemtuzumab, 1 mg
J0480	Injection, basiliximab, 20 mg
J0485	Injection, belatacept, 1 mg
J0490	Injection, belimumab, 10 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J0638	Injection, canakinumab, 1 mg
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J1300	Injection, eculizumab, 10 mg
J1302	Injection, sutimlimab-jome, 10 mg
J1303	Injection, ravulizumab-cwvz, 10 mg
J1438	Injection, etanercept, 25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 mcg
J1447	Injection, tbo-filgrastim, 1 mcg

J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1595	Injection, glatiramer acetate, 20 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J1823	Injection, inebilizumab-cdon, 1 mg
J1826	Injection, interferon beta-1a, 30 mcg
J1830	Injection interferon beta-1b, 0.25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J2323	Injection, natalizumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J2329	Injection, ublituximab-xiiy, 1mg
J2350	Injection, ocrelizumab, 1 mg
J2355	Injection, oprelvekin, 5 mg
J2504	Injection, pegademase bovine, 25 IU
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
J2562	Injection, plerixafor, 1 mg
J2781	Injection, pegcetacoplan, intravitreal, 1 mg
J2793	Injection, rilonacept, 1 mg
J2820	Injection, sargramostim (GM-CSF), 50 mcg
J2860	Injection, siltuximab, 10 mg
J3241	Injection, teprotumumab-trbw, 10 mg

J3245	Injection, tildrakizumab, 1 mg J3380 Injection, vedolizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J7500-J7599:	Immunosuppressive drugs
J8560	Etoposide, oral, 50 mg
J8610	Methotrexate, oral, 2.5 mg
J9000	Injection, doxorubicin HCl, 10 mg
J9015	Injection, aldesleukin, per single use vial
J9030	BCG live intravesical instillation, 1 mg
J9037	Injection, belantamab mafodotin-blmf, 0.5 mg
J9040	Injection, bleomycin sulfate, 15 units
J9060	Injection, cisplatin, powder or solution, 10 mg
J9065	Injection, cladribine, per 1 mg J9047 Injection, carfilzomib, 1 mg
J9070	Cyclophosphamide, 100 mg
J9071	Injection, cyclophosphamide, (AuroMedics), 5 mg
J9098	Injection, cytarabine liposome, 10 mg
J9100	Injection, cytarabine, 100 mg
J9145	Injection, daratumumab, 10 mg
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine
J9176	Injection, elotuzumab, 1 mg
J9181	Injection, etoposide, 10 mg

J9190	Injection, fluorouracil, 500 mg
J9205	Injection, irinotecan liposome, 1 mg
J9206	Injection, irinotecan, 20 mg
J9210	Injection, emapalumab-lzsg, 1 mg
J9212	Injection, interferon alfacon-1, recombinant, 1 mcg
J9213	Injection, interferon, alfa-2a, recombinant, 3 million units
J9214	Injection, interferon, alfa-2b, recombinant, 1 million units
J9215	Injection, interferon, alfa-N3, (human leukocyte derived), 250,000 IU
J9216	Injection, interferon, gamma 1-b, 3 million units
J9247	Injection, melphalan flufenamide, 1 mg
J9250	Methotrexate sodium, 5 mg
J9259	Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to J9264, 1 mg
J9260	Methotrexate sodium, 50 mg
J9264	Injection, paclitaxel protein-bound particles, 1 mg
J9267	Injection, paclitaxel, 1 mg
J9302	Injection, ofatumumab, 10 mg
J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Vincristine sulfate, 1 mg
J9371	Injection, vincristine sulfate liposome, 1 mg
J9380	Injection, teclistamab-cqyv, 0.5 mg

M0249	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation
M0250	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation
Q0249	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal
Q0510	Pharmacy supply fee for initial immunosuppressive drug(s), first month following transplant
Q2043	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion
Q2049	Injection, doxorubicin HCl, liposomal, imported Lipodox, 10 mg
Q2050	Injection, doxorubicin HCl, liposomal, not otherwise specified, 10 mg
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Q2055	Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Q3027	Injection, interferon beta-1a, 1 mcg for intramuscular use
Q3028	Injection, interferon beta-1a, 1 mcg for subcutaneous use
Q5101	Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg

Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5108	Injection, pegfilgrastim-jmdb (Fulphila), biosimilar, 0.5 mg
Q5109	Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg Q5121 Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg
Q5120	Injection, pegfilgrastim-bmez (ZIEXTENZO), biosimilar, 0.5 mg
Q5122	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg
Q5131	Injection, adalimumab-aacf (Idacio), biosimilar, 20 mg
S0145	Injection, PEGylated interferon alfa-2A, 180 mcg per ml
S0148	Injection, PEGylated interferon alfa-2B, 10 mcg
S0172	Chlorambucil, oral, 2 mg

17.4.2.2. Corticosteroids

AHFS 680400* Adrenals, restricted to oral routes of administration

17.4.2.2.1. ICD-10-CM, CPT[13] and HCPSC Codes

In addition to NDC codes for the above, the following ICD-10, CPT and HCPCS codes will be used:

ICD-10-CM

T38.0**	Poisoning by, adverse effect of and underdosing of glucocorticoids and synthetic analogues
T50.0X*	Poisoning by, adverse effect of and underdosing of mineralocorticoids and their antagonists

CPT

4135F	Systemic corticosteroids Rx
4136F	Systemic corticosteroids not Rx
4140F	Inhaled corticosteroids prescribed
4194F	Patient receiving =>10 mg daily prednisone (or equivalent) for longer than 6 months, and improvement or no change in disease activity (RA)

HCPCS

G2113	Patient receiving >5 mg daily prednisone (or equivalent) for longer than 6 months, and improvement or no change in disease activity
J0702	Injection, betamethasone acetate 3mg and betamethasone sodium phosphate 3 mg
J1020	Injection, methylprednisolone acetate, 20 mg
J1030	Injection, methylprednisolone acetate, 40 mg
J1040	Injection, methylprednisolone acetate, 80 mg
J1094	Injection, dexamethasone acetate, 1 mg
J1095	Injection, dexamethasone 9%, intraocular, 1 mcg
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg

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J1100	Injection, dexamethasone sodium phosphate, 1 mg
J1700	Injection, hydrocortisone acetate, up to 25 mg
J1710	Injection, hydrocortisone sodium phosphate, up to 50 mg
J1720	Injection, hydrocortisone sodium succinate, up to 100 mg
J2650	Injection, prednisolone acetate, up to 1 ml
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg
J3299	Injection, triamcinolone acetonide (Xipere), 1 mg
J3300	Injection, triamcinolone acetonide, preservative free, 1 mg
J3301	Injection, triamcinolone acetonide, not otherwise specified, 10 mg
J3302	Injection, triamcinolone diacetate, per 5 mg
J3303	Injection, triamcinolone hexacetonide, per 5 mg
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
J7311	Injection, fluocinolone acetonide, intravitreal implant (Retisert), 0.01 mg
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg
J7313	Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg
J7402	Mometasone furoate sinus implant, (Sinuva), 10 mcg
J7509	Methylprednisolone, oral, per 4 mg
J7510	Prednisolone, oral, per 5 mg
J7512	Prednisone, immediate release or delayed release, oral, 1 mg

J7622	Beclomethasone, inhalation solution, compounded product, administered through DME, unit dose form, per mg
J7624	Betamethasone, inhalation solution, compounded product, administered through DME, unit dose form, per mg
J7626	Budesonide, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, up to 0.5 mg
J7627	Budesonide, inhalation solution, compounded product, administered through DME, unit dose form, up to 0.5 mg
J7633	Budesonide, inhalation solution, FDA-approved final product, noncompounded, administered through DME, concentrated form, per 0.25 mg
J7634	Budesonide, inhalation solution, compounded product, administered through DME, concentrated form, per 0.25 mg
J7637	Dexamethasone, inhalation solution, compounded product, administered through DME, concentrated form, per mg
J7638	Dexamethasone, inhalation solution, compounded product, administered through DME, unit dose form, per mg
J7641	Flunisolide, inhalation solution, compounded product, administered through DME, unit dose form, per mg
J7683	Triamcinolone, inhalation solution, compounded product, administered through DME, concentrated form, per mg
J7684	Triamcinolone, inhalation solution, compounded product, administered through DME, unit dose form, per mg
J8540	Dexamethasone, oral, 0.25 mg

17.4.2.3. Antivirals

The below list includes generic drug names. All associated NDC codes will be utilized. Additional therapies may be added as they are approved.

17.4.2.3.1. Topical

acyclovir
docosanol
penciclovir

17.4.2.3.2. Eye

fomivirsen
ganciclovir
idoxuridine
trifluridine
vidarabine

17.4.2.3.3. General Antivirals

acyclovir
baloxavir marboxil
brincidofovir
cidofovir
famciclovir
foscarnet
ganciclovir
letermovir
maribavir
oseltamivir
peramivir
ribavirin
rimantadine
tecovirimat
valacyclovir
zanamivir

17.4.2.3.4. HIV-Specific

abacavir
amprenavir
atazanavir
cabotegravir
cobicistat (in combination with others)
darunavir
delavirdine
didanosine
dolutegravir
doravirine
efavirenz

elvitegravir
emtricitabine
enfuvirtide
etravirine
fosamprenavir
fostemsavir
indinavir
lamivudine
lopinavir
maraviroc
nelfinavir
nevirapine
raltegravir
rilpivirine
ritonavir
saquinavir
stavudine
tenofovir
tipranavir
zalcitabine
zidovudine

17.4.2.3.5. ICD-10-CM, CPT[14] and HCPCS Codes

In addition to NDC codes for the above, the following CPT and HCPCS codes will be used:

ICD-10-PCS

XW0DX38	Introduction of Maribavir Anti-infective into Mouth and Pharynx, External Approach, New Technology Group 8
XW0G738	Introduction of Maribavir Anti-infective into Upper GI, Via Natural or Artificial Opening, New Technology Group 8
XW0H738	Introduction of Maribavir Anti-infective into Lower GI, Via Natural or ArtificialOpening, New Technology Group 8

CPT[15]

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4150F	Patient receiving antiviral treatment for Hepatitis C (HEP-C)
4153F	Combination peginterferon and ribavirin therapy prescribed (HEP-C)

HCPCS

J0133	Injection, acyclovir, 5 mg
J0739	Injection, cabotegravir, 1 mg
J0740	Injection, cidofovir, 375 mg
J0741	Injection, cabotegravir and rilpivirine, 2 mg/3 mg
J1324	Injection, enfuvirtide, 1 mg
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg
J1455	Injection, foscarnet sodium, per 1,000 mg
J1570	Injection, ganciclovir sodium, 500 mg
J1574	Injection, ganciclovir sodium (Exela) not therapeutically equivalent to J1570, 500 mg
J2547	Injection, peramivir, 1 mg
J3485	Injection, zidovudine, 10 mg
J7310	Ganciclovir, 4.5 mg, long-acting implant
S0104	Zidovudine, oral, 100 mg
S0137	Didanosine (ddI), 25 mg
S0140	Saquinavir, 200 mg

17.4.2.4. Antibiotics

The below list includes generic drug names, organized by therapeutic class codes and hierarchical ingredient codes developed by First Databank. Therapeutic class codes (THERSPEC) and the Hierarchical Ingredient Code List (HICL) are proprietary to First Databank. All associated NDC codes will be utilized. Additional therapies may be added as they are approved.

17.4.2.4.1. Vaginal

clindamycin
metronidazole

17.4.2.4.2. Topical

bacitracin
chloramphenicol
clindamycin
doxycycline
erythromycin
gentamicin
meclocycline
minocycline
mupirocin
neomycin
ozenoxacin
tetracycline

17.4.2.4.3. Eye and Ear

azithromycin
bacitracin
besifloxacin
cefuroxime
chloramphenicol
ciprofloxacin
erythromycin
gatifloxacin
gentamicin
levofloxacin
moxifloxacin
natamycin
neomycin
norfloxacin
ofloxacin
oxytetracycline
polymyxin

tetracycline
tobramycin
vancomycin

17.4.2.4.4. Nose

mupirocin

17.4.2.4.5. Antitubercular

bedaquiline
capreomycin
cycloserine
ethambutol
isoniazid
pretomanid
pyrazinamide
rifampin
rifapentine

17.4.2.4.6. Broad Spectrum

17.4.2.4.6.1. Penicillin Antibiotics

amoxicillin
ampicillin
bacampicillin
carbenicillin
cloxacillin
dicloxacillin
mezlocillin
nafcillin
oxacillin
penicillin
piperacillin
ticarcillin

17.4.2.4.6.2. Tetracycline Antibiotics

demeclocycline
doxycycline
eravacycline
minocycline
omadacycline
oxytetracycline
sarecycline
tetracycline

17.4.2.4.6.3. Macrolide Antibiotics

azithromycin
clarithromycin
dirithromycin
erythromycin
fidaxomicin
troleandomycin

17.4.2.4.6.4. Chloramphenicol Antibiotics and Derivatives

chloramphenicol

17.4.2.4.6.5. Aminoglycoside Antibiotics

amikacin
gentamicin
kanamycin
neomycin
netilmicin
plazomicin
streptomycin
tobramycin

17.4.2.4.6.6. Aminocyclitol Antibiotics

spectinomycin

17.4.2.4.6.7. Vancomycin Antibiotics and Derivatives

vancomycin

17.4.2.4.6.8. Lincosamide Antibiotics

clindamycin
lincomycin

17.4.2.4.6.9. Antibiotics, Miscellaneous, Other

bacitracin
novobiocin

17.4.2.4.6.10. Streptogramin Antibiotics

dalfopristin
quinupristin

17.4.2.4.6.11. Polymyxin Antibiotics and Derivatives

colistin
polymyxin

17.4.2.4.6.12. Oxazolidinone Antibiotics

linezolid
tedizolid

17.4.2.4.6.13. Quinolone Antibiotics

alatrofloxacin
cinoxacin
ciprofloxacin
delafloxacin
enoxacin
gatifloxacin
gemifloxacin
grepafloxacin
levofloxacin
lomefloxacin
moxifloxacin
nalidixic acid
norfloxacin

ofloxacin
sparfloxacin
trovafloxacin

17.4.2.4.6.14. Carbapenem Antibiotics (Thenamycins)

doripenem
ertapenem
imipenem
meropenem

17.4.2.4.6.15. Cephalosporin Antibiotics

cefaclor
cefadroxil
cefamandole
cefazolin
cefdinir
cefditoren
cefepime cefiderocol
cefixime
cefonicid
cefoperazone
cefotaxime
cefotetan
cefoxitin
cefpodoxime
cefprozil
ceftazidime
ceftibuten
ceftizoxime
ceftolozane
ceftriaxone
cefuroxime
cephalexin
cephalothin
cephapirin
cephradine
loracarbef

17.4.2.4.6.16. Antifungal Antibiotics

amphotericin b
anidulafungin
caspofungin
griseofulvin
ibrexafungerp
micafungin
nystatin
rezafungin

17.4.2.4.6.17. Ketolide Antibiotics

telithromycin

17.4.2.4.6.18. Rifamycins and Related Derivative Antibiotics

rifamycin
rifaximin

17.4.2.4.6.19. Lipoglycopeptide Antibiotics

dalbavancin
oritavancin
telavancin

17.4.2.4.7. ICD-10-CM, CPT[16], and HCPCS Codes

In addition to NDC codes for the above, the following CPT and HCPCS codes will be used:

ICD-10-CM

T36.***	Poisoning by, adverse effect of and underdosing of systemic antibiotics

ICD-10-PCS

XW033R9	Introduction of Rezafungin into Peripheral Vein, Percutaneous Approach, New Technology Group 9

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XW043R9	Introduction of Rezafungin into Central Vein, Percutaneous Approach, New Technology Group 9

CPT

4045F	Appropriate empiric antibiotic prescribed (CAP), (EM)
4046F	Documentation that prophylactic antibiotics were given within 4 hours prior to surgical incision or given intraoperatively (PERI 2)
4047F	Documentation of order for prophylactic parenteral antibiotics to be given within 1 hour (if fluoroquinolone or vancomycin, 2 hours) prior to surgical incision (or start of procedure when no incision is required) (PERI 2)
4048F	Documentation that administration of prophylactic parenteral antibiotic was initiated within 1 hour (if fluoroquinolone or vancomycin, 2 hours) prior to surgical incision (or start of procedure when no incision is required) as ordered (PERI 2)
4120F[17]	Antibiotic prescribed or dispensed (URI, PHAR), (A-BRONCH)
80150	Amikacin
80170	Gentamicin
80200	Tobramycin
80202	Vancomycin

HCPCS

C9462	Injection, delafloxacin, 1 mg
G8710	Patient prescribed antibiotic
G8711	Prescribed antibiotic on or within 3 days after the episode date
G9498	Antibiotic regimen prescribed
G9505	Antibiotic regimen prescribed within 10 days after onset of symptoms for documented medical reason

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G8916	Patient with preoperative order for IV antibiotic surgical site infection (SSI) prophylaxis, antibiotic initiated on time
G9286	Antibiotic regimen prescribed within 10 days after onset of symptoms
G9315	Amoxicillin, with or without clavulanate, prescribed as a first line antibiotic at the time of diagnosis
G9712	Documentation of medical reason(s) for prescribing or dispensing antibiotic (e.g., intestinal infection, pertussis, bacterial infection, lyme disease, otitis media, acute sinusitis, acute pharyngitis, acute tonsillitis, chronic sinusitis
J0120	Injection, tetracycline, up to 250 mg
J0121	Injection, omadacycline, 1 mg
J0122	Injection, eravacycline, 1 mg
J0200	Injection, alatrofloxacin mesylate, 100 mg
J0278	Injection, amikacin sulfate, 100 mg
J0285	Injection, amphotericin B, 50 mg
J0287	Injection, amphotericin B lipid complex, 10 mg
J0288	Injection, amphotericin B cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin B liposome, 10 mg
J0290	Injection, ampicillin sodium, 500 mg
J0291	Injection, plazomicin, 5 mg
J0295	Injection, ampicillin sodium/sulbactam sodium, per 1.5 g
J0348	Injection, anidulafungin, 1 mg
J0349	Injection, rezafungin, 1 mg
J0456	Injection, azithromycin, 500 mg
J0558	Injection, penicillin G benzathine and penicillin G procaine, 100,000 units
J0561	Injection, penicillin G benzathine, 100,000 units

J0637	Injection, caspofungin acetate, 5 mg
J0689	Injection, cefazolin sodium (Baxter), not therapeutically equivalent to J0690, 500 mg
J0690	Injection, cefazolin sodium, 500 mg
J0692	Injection, cefepime HCl, 500 mg
J0694	Injection, cefoxitin sodium, 1 g
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg
J0696	Injection, ceftriaxone sodium, per 250 mg
J0697	Injection, sterile cefuroxime sodium, per 750 mg
J0698	Injection, cefotaxime sodium, per g
J0699	Injection, cefiderocol, 10 mg
J0701	Injection, cefepime HCl (Baxter), not therapeutically equivalent to Maxipime, 500 mg
J0703	Injection, cefepime HCl (B. Braun), not therapeutically equivalent to Maxipime, 500 mg
J0710	Injection, cephapirin sodium, up to 1 g
J0713	Injection, ceftazidime, per 500 mg
J0714	Injection, ceftazidime and avibactam, 0.5 g/0.125 g
J0715	Injection, ceftizoxime sodium, per 500 mg
J0720	Injection, chloramphenicol sodium succinate, up to 1 g
J0736	Injection, clindamycin phosphate, 300 mg
J0737	Injection, clindamycin phosphate (Baxter), not therapeutically equivalent to J0736, 300 mg
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg
J0743	Injection, cilastatin sodium; imipenem, per 250 mg
J0744	Injection, ciprofloxacin for intravenous infusion, 200 mg

J0875	Injection, dalbavancin, 5 mg
J0878	Injection, daptomycin, 1 mg
J1267	Injection, doripenem, 10 mg
J1335	Injection, ertapenem sodium, 500 mg
J1364	Injection, erythromycin lactobionate, per 500 mg
J1580	Injection, garamycin, gentamicin, up to 80 mg
J1836	Injection, metronidazole, 10 mg
J1840	Injection, kanamycin sulfate, up to 500 mg
J1850	Injection, kanamycin sulfate, up to 75 mg
J1890	Injection, cephalothin sodium, up to 1 g
J1956	Injection, levofloxacin, 250 mg
J2010	Injection, lincomycin HCl, up to 300 mg
J2020	Injection, linezolid, 200 mg
J2021	Injection, linezolid (Hospira) not therapeutically equivalent to J2020, 200 mg
J2184	Injection, meropenem (B. Braun) not therapeutically equivalent to J2185, 100 mg
J2185	Injection, meropenem, 100 mg
J2186	Injection, meropenem, vaborbactam, 10 mg/10 mg, (20 mg)
J2247	Injection, micafungin sodium (Par Pharm) not therapeutically equivalent to J2248, 1 mg
J2248	Injection, micafungin sodium, 1 mg
J2265	Injection, minocycline HCl, 1 mg
J2280	Injection, moxifloxacin, 100 mg
J2281	Injection, moxifloxacin (Fresenius Kabi) not therapeutically equivalent to J2280, 100 mg

J2406	Injection, oritavancin (Kimyrsa), 10 mg
J2407	Injection, oritavancin (Orbactiv), 10 mg
J2460	Injection, oxytetracycline HCl, up to 50 mg
J2510	Injection, penicillin G procaine, aqueous, up to 600,000 units
J2540	Injection, penicillin G potassium, up to 600,000 units
J2543	Injection, piperacillin sodium/tazobactam sodium, 1 g/0.125 g (1.125 g)
J2700	Injection, oxacillin sodium, up to 250 mg
J2770	Injection, quinupristin/dalfopristin, 500 mg (150/350)
J3000	Injection, streptomycin, up to 1 g
J3090	Injection, tedizolid phosphate, 1 mg
J3095	Injection, telavancin, 10 mg
J3260	Injection, tobramycin sulfate, up to 80 mg
J3320	Injection, spectinomycin dihydrochloride, up to 2 g
J3370	Injection, vancomycin HCl, 500 mg
J3371	Injection, vancomycin HCl (Mylan) not therapeutically equivalent to J3370, 500 mg
J3372	Injection, vancomycin HCl (Xellia) not therapeutically equivalent to J3370, 500 mg
J7342	Instillation, ciprofloxacin otic suspension, 6 mg
J7682	Tobramycin, inhalation solution, FDA-approved final product, noncompounded, unit dose form, administered through DME, per 300 mg
J7685	Tobramycin, inhalation solution, compounded product, administered through DME, unit dose form, per 300 mg
Q0144	Azithromycin dihydrate, oral, capsules/powder, 1 g
S0021	Injection, cefoperazone sodium, 1 g

S0032	Injection, nafcillin sodium, 2 g
S0034	Injection, ofloxacin, 400 mg
S0040	Injection, ticarcillin disodium and clavulanate potassium, 3.1 g
S0074	Injection, cefotetan disodium, 500 mg
S0081	Injection, piperacillin sodium, 500 mg

18. ANNEX 3. ADDITIONAL INFORMATION

Not applicable.

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