
PASS Protocol

Active substance Tixagevimab/Cilgavimab

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***A Non-interventional Multi-country Cohort Study to Assess the
Safety of EVUSHELD™ (Tixagevimab/Cilgavimab) During
Pregnancy***

Marketing Authorisation Holder(s)

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Approved by:

Digitally signed

Date: 2022.09.22

Date

PASS INFORMATION

Title	O-STEREO Study: A non-interventional multi-country cohort study to assess the safety of EVUSHELD™ (Tixagevimab/Cilgavimab) during pregnancy
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Joint PASS	No
Research question and objectives	Research question: What are the pregnancy and offspring (neonatal and infant) outcomes following EVUSHELD exposure among pregnancies in women of child-bearing potential eligible for EVUSHELD treatment? Objectives: To characterise the risk of pregnancy and offspring (neonatal and infant) outcomes in pregnancies with and without exposure to EVUSHELD among women of child-bearing indicated for such treatment in the real-world setting.

Country (-ies) of study	Canada, France and the United States of America (US)
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2 LIST OF ABBREVIATIONS

Abbreviation or special term	Explanation
AE	Adverse Event
AEP	Action Evidence Platform
AIDS	Acquired Immune Deficiency Syndrome
ART	Assisted reproductive technology
ASD	Absolute Standardised mean Difference
ATC	Anatomical Therapeutic Chemical
BMI	Body Mass Index. Calculated as kg/m ² ; below 18.5: underweight; 18.5-24.9: normal weight; 30 and above: obesity.
BPE	Bordeaux PharmacoEpi
CaMCCo	Canadian Mother Child Cohort
C-section	Caesarean Section
CCAM	Classification Commune des Actes Médicaux
CEM	Coarsened exact matching
CI	Confidence Interval
CNAM	French National Health Insurance Fund
COPD	Chronic obstructive pulmonary disease
COVID-19	Coronavirus disease 2019
DCIR	Datamart de Consommation Inter-Regimes
EMA	European Medicine Agency
ENCePP	The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EHR	Electronic Health Records
EMR	Electronic Medical Records
EPE	End of Pregnancy Episode
EU	European Union
EUA	Emergency Use Authorisation
FDA	Food and Drug Administration
GA	Gestational age
GAIA	Global Alignment of Immunisation Safety Assessment in Pregnancy
GPP	Green Public Procurement
GVP	Good pharmacovigilance practices
hdPS	High-Dimensional Propensity Score
HIPAA	Health Insurance Portability and Accountability Act

Abbreviation or special term	Explanation
HIV	Human Immunodeficiency Virus
HCPCS	Healthcare Common Procedure Coding System (collection of standardised codes that represent medical procedures, supplies, products and services in the US)
HPV	Human papillomavirus
HSV	Herpes Simplex Virus
HV MOM	Heath Verity Maternal Outcomes Masterset
ICD	International Classification of Diseases
ICH GCPs	International Council for Harmonisation Good Clinical Practice
ICMJE	International Committee of Medical Journal Editors
ICSI	IntraCytoplasmic Sperm Injection
IQR	Interquartile range
IRB	Institutional Review Board
IVF	In Vitro Fertilisation
kg	Kilograms
LMP	Last Menstrual Period
LBW	Low Birth Weight
mg	Milligrams
MNS	Midwives Notification Scheme
N	Number of cases
n	Number of patients
NDC	National Drug Code (for the US)
NSW	New South Wales
p	Observed proportion of events
PAS	Post-authorisation study
PASS	Post-Authorisation Safety Study
PBS	Pharmaceutical Benefits Scheme
PDC	Perinatal Data Collection
PMSI	Programme de Médicalisation des Systèmes d'Information
PPV	Positive Predictive Value
PS	Propensity Score
RMP	Risk Management Plan
RR	Risk ratio
SAP	Statistical Analysis Plan
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2

Abbreviation or special term	Explanation
SAS	Statistical Analytical System
SCID	Severe combined immunodeficiency
SD	Standard deviation
SGA	Small for gestational age
SI-DEP	Système d'Informations de DEPistage
SNDS	Système National des Données de Santé
SOGC	Society of Obstetricians and Gynaecologists of Canada
SPIFD	Structured process to identify fit-for-purpose data
TNF	Tumour Necrosis Factor
US	United States of America
VAC-SI	Système d'Information Vaccin Covid
WCG	Wirb Copernicus Group
WHO	World Health Organisation

3 RESPONSIBLE PARTIES

Name	Professional title	Role in study	Affiliation	Email address
		Study lead	AstraZeneca	
		Biostatistician	AstraZeneca	
		Senior reviewer	AstraZeneca	
		Study lead	Action	
		Biostatistician	Action	

4 ABSTRACT

Title: O-STEREO Study: A non-interventional multi-country cohort study to assess the safety of EVUSHELD™ (Tixagevimab/Cilgavimab) during pregnancy

V1.0 19 September 2022

Main author:

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Rationale and background:

Despite the widespread use of over 11 billion doses of Coronavirus disease 2019 (COVID-19) vaccines, certain populations do not achieve sufficient immune response or are ineligible to receive the COVID-19 vaccine. Within this patient population, women with high-risk conditions (including but not limited to cancer, solid organ transplant, human immunodeficiency virus/acquired immune deficiency syndrome [HIV/AIDS], prolonged systemic corticosteroid use, immunodeficiencies, autoimmune conditions and immune-mediated inflammatory disorders; refer to Section 9.2.2), may become pregnant and are at increased risk of adverse outcomes from COVID-19 disease. Given that pregnancy is a state of weakened immunity, this population is at even higher risk of adverse perinatal outcomes from COVID-19. As an alternative or in addition to vaccination, COVID-19 pre-exposure prophylaxis with monoclonal antibody therapy can protect against COVID-19-related morbidity and mortality in such high-risk populations. EVUSHELD™ (tixagevimab, cilgavimab) is a long-acting monoclonal antibody combination therapy for prevention of COVID-19. For ethical reasons, pregnant women were excluded from EVUSHELD clinical studies and therefore, there are no data on patients receiving EVUSHELD throughout their pregnancy, or on their offspring. It is imperative to fully understand the safety profile associated with EVUSHELD exposure during pregnancy as use in this population occurs in the real-world and as post-authorisation data become available internationally.

This non-interventional multi-country cohort study or post-authorisation safety study (PASS) in pregnancy has been designed to fulfil EVUSHELD's pharmacovigilance plan as specified in the Core Risk Management Plan (RMP), and notably in the additional pharmacovigilance activities in the EVUSHELD EU RMP.

Research question and objectives:

What are the pregnancy and offspring (neonatal and infant) outcomes following EVUSHELD exposure among pregnancies in women of child-bearing potential eligible for EVUSHELD treatment?

The primary objectives of this study are to:

- 1 Describe the risk of pregnancy outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies. Outcomes of interest include spontaneous abortion, pre-eclampsia, ectopic pregnancy, maternal death, gestational diabetes, gestational hypertension, preterm live birth, and stillbirth.
- 2 Describe the risk of offspring outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies.
- 3 Neonatal outcomes of interest include: low birth weight, small for gestational age (SGA), respiratory distress syndrome in the newborn, and neonatal death.
- 4 Infant outcomes of interest include: major congenital malformations, infant death, and failure to thrive.

The secondary objectives of this study are to:

- 1 Describe EVUSHELD utilisation patterns, including number of doses, cumulative dose, and duration of treatment, among EVUSHELD-exposed pregnancies.
- 2 Describe the risk of the pregnancy and offspring outcomes listed above among EVUSHELD-exposed pregnancies (maternal age, high-risk condition type, trimester of index date, recent Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) infection, timing of last SARS-COV-2 vaccination relative to gestation, and other SARS-COV-2 monoclonal antibody).

Pending sufficient sample size requirements at the final analysis only, the exploratory objectives of this study are to estimate the risk ratios and risk differences between exposed and matched unexposed pregnancies:

- 1 Compare the risk of pregnancy outcomes in matched EVUSHELD-exposed and unexposed pregnancies. Outcomes of interest include: spontaneous abortion, preterm live birth, ectopic pregnancy, maternal death, and stillbirth.
- 2 Compare the risk of offspring outcomes in matched EVUSHELD-exposed and unexposed pregnancies.
 - (a) Neonatal outcomes of interest include: neonatal death, and SGA.
 - (b) Infant outcomes of interest include: major congenital malformations.

Study design:

This is a multi-country, non-interventional cohort study in pregnancies exposed to EVUSHELD and pregnancies unexposed to EVUSHELD among women eligible for EVUSHELD. The study will be conducted within secondary data sources (administrative claims, electronic medical records (EMR) and/or registry data). For each country, the overall study period will span 12 months prior to the country-specific EVUSHELD availability until the end of the data cut or 31 March 2027, whichever is earlier.

The assessment of each pregnancy and offspring outcome will involve creating distinct analytic cohorts whose design is tailored to the aspects of the outcome, such as the timeframe of its ascertainment, the etiologically relevant exposure window, and relevant gestational age. To facilitate characterisation of outcomes in comparable groups, each analytic cohort will consist of EVUSHELD-exposed pregnancies that are matched to unexposed pregnancies for contextualisation purposes. For EVUSHELD-exposed pregnancies, the index date reflects the first date of EVUSHELD exposure during the exposure ascertainment period. For unexposed pregnancies, the index date is the clinical activity date (ie, the date of any healthcare encounter, or LMP when the index date for the exposed pregnancy is LMP, or 20th week gestation when the index date for the exposed pregnancy is the 20th week gestation for those outcomes studies from this period) within, at most, 14 days of the index date of a matched EVUSHELD-exposed pregnancy when EVUSHELD injection occurs from the first day of the exposure ascertainment period. In cases where the EVUSHELD injection occurs before the first day of the exposure ascertainment period (ie, the index date is LMP, or the 20th week gestation for those outcomes studied from this period), a clinical activity in the unexposed pregnancy within, at most, 14 days of EVUSHELD injection is necessary to be selected. The index date will be defined as the date of birth for the analysis of offspring outcomes. Pending sufficient sample size requirements at the final analysis only, exploratory comparative analyses will be performed on selected outcomes that are of most importance in pregnancy safety studies with the intent of safety surveillance. Pregnancy outcomes and offspring outcomes will be the units of analysis for this study, and a single individual can contribute more than one pregnancy to an analytic cohort.

Population:

The study will include pregnancies in individuals eligible for EVUSHELD therapy in each country in the selected datasets, including pregnant individuals aged 18 to 49 years with a high-risk condition documented in the 12 months prior to the start of the pregnancy, defined as the first day of the last menstrual period (LMP).

Pregnancies meeting the following criteria will be included within each analytic cohort:

Inclusion criteria

- Female sex at LMP

- Age 18-49 years at LMP
- Continuous coverage/clinical activity (dependent on data source type) within the confounder ascertainment period, as defined in [Table 3](#)
- LMP date falls within the LMP eligibility period, as defined in [Table 3](#)
- Occurrence of at least one condition conferring high risk for adverse COVID-19 outcomes during the confounder ascertainment period

Exclusion criterion

- Multifoetal pregnancies will be excluded
- In vitro fertilisation or other assisted reproductive technology in the 36-week prior LMP

Variables:

Exposure:

A pregnancy is considered exposed to EVUSHELD if 1 of 2 conditions are met: (1) EVUSHELD was received during the 36-week period [reflective of roughly 3 half-lives of EVUSHELD] prior to LMP, or (2) EVUSHELD was received on/after LMP during the exposure ascertainment period, which will vary based on the outcome of interest.

EVUSHELD administration will be captured via pharmacy claims and/or prescription information in EMR using Anatomical Therapeutic Chemical (ATC) code J06BD03, non-proprietary name AZD7442, drug name tixagevimab and cilgavimab, US National Drug Code (NDC) code 0310-7442 or any other appropriate local product code.

For pregnancies with EVUSHELD exposure, the past exposure (eg, exposure prior to the 36-week pre-pregnancy period), prior exposure duration (eg, 36 weeks prior to LMP), pregnancy period at first dose, time to second dose (if applicable), cumulative dose, total number of doses and total exposure duration will be described. Cumulative dose is determined by the number of doses administered.

Outcomes:

All outcomes will be assessed descriptively; a subset of outcomes will be examined comparatively (denoted below by *; see [Table 3](#)). Outcomes definitions are based on validated algorithms from previous studies, where available, and determined to be appropriate specifically for use of secondary data. The outcome assessment period varies across the type of analytic cohort, reflecting the tailored study design approach needed for each outcome.

Pregnancy outcomes: spontaneous abortion*, pre-eclampsia, ectopic pregnancy*, maternal death*, gestational diabetes, gestational hypertension, preterm live birth*, stillbirth*.

Neonatal outcomes: low birth weight, SGA*, respiratory distress syndrome in the newborn, neonatal death*.

Infant outcomes: major congenital malformations*, infant death, and failure to thrive.

Covariates:

Covariates will be assessed descriptively during a time period relevant to the covariate under assessment. Selected covariates identified as potential confounders will be considered for propensity score (PS) matching in the exploratory analysis.

Pregnancy-related covariates: demographics, pregnancy characteristics (gestational age at index date, care setting at delivery, caesarean section delivery, prior pregnancy history, maternal parity history, and pre-pregnancy body mass index [BMI]), comorbidities (including high-risk conditions), co-medications and substance abuse, COVID-19 vaccine and disease.

Offspring covariates: sex, breastfed, infections.

Data sources:

This study will use data from multiple existing secondary healthcare databases that cover a large population, contain a mother-baby linkage, high quality data on COVID-19 monoclonal antibodies (including EVUSHELD exposure information), pregnancy and birth outcomes, and important covariates.

The following datasets are considered for this study:

- Canada: Canadian Mother Child Cohort
- France: Système National des Données de Santé
- US: HealthVerity: Maternal Outcomes Masterset

Study size:

Precision calculations were performed for the primary analyses. These calculations are based on the prevalence of outcomes of interest in the absence of EVUSHELD exposure. Values of 0.01 represent the observed prevalence of outcomes such as stillbirth and ectopic pregnancy. A prevalence close to 0.05 is relevant for outcomes like major congenital malformations. Outcomes such as preterm birth and small for gestational age have a prevalence of approximately 0.10. Spontaneous abortions have an observed prevalence close to 0.15.

For the primary analyses, the 95% confidence interval (CI) (using the Wilson method) for each background prevalence for a given number of pregnancies are presented below. For example, a sample size of 100 pregnancies examining preterm birth and assuming a true prevalence of 0.10 would result in a 95% CI estimate for prevalence of 0.055 to 0.174. These CIs would apply regardless of the EVUSHELD exposure status and are based on background prevalence estimates in unexposed patients.

Background prevalence	Sample size				
	50	75	100	150	200
0.01	0.004; 0.105*	0.002; 0.072*	0.002; 0.054	0.004; 0.047*	0.003; 0.036
0.05	0.021; 0.162*	0.021; 0.129*	0.022; 0.112	0.027; 0.102*	0.027; 0.090
0.10	0.043; 0.214	0.055; 0.197*	0.055; 0.174	0.062; 0.158	0.066; 0.149
0.15	0.083; 0.285*	0.094; 0.259*	0.093; 0.233	0.104; 0.220*	0.107; 0.206

*For calculation purposes, the number of events (successes of the binomial distribution) was rounded up to an integer (minimum 1). For example, when the background prevalence is 0.01 and the sample size is 50, the number of events was set to one. If the prevalence was 0.05 and the sample size was 75, the number of events was set to 4.

Considering potential rare exposure and low background prevalence of some outcomes, the cumulative binomial probability of observing at least one and five events is presented as a function of sample size in the Section [9.5](#).

Data analysis:

Data from the US will be analysed using the Action Evidence Platform (AEP). Data from countries other than the US will be analysed separately by research partners on the basis of this protocol. Database-specific results of each descriptive and exploratory comparative analysis in aggregated format will be pooled together using meta-analysis. All analyses will be further described in the final Statistical Analysis Plan (SAP) and will be included in the final report.

Coarsened exact matching

Based on the etiologically relevant exposure window and outcome assessment period, the outcomes of interest fall into 5 outcome types:

- Pregnancy outcomes:
 - Pregnancy outcomes potentially associated with exposure in early pregnancy and measured prior to 20 weeks gestation
 - Pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured anytime during pregnancy
 - Pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured after 20 weeks gestation
- Offspring outcomes:
 - Neonatal outcomes measured in the first 28 days of life

- Infant outcomes measured in the first year of life

For each of these five outcome types, a distinct analytic cohort will be created in which each eligible EVUSHELD exposed pregnancy will be matched to all possible unexposed pregnancies using coarsened exact matching (CEM) (CEM matched set).

For each analytic cohort, exposed pregnancies will be matched to as many unexposed pregnancies as possible based on maternal age (with at most ± 2 years window), index date (with at most ± 14 days window), LMP date (with at most ± 14 days window), and high-risk condition group (severely immunocompromised, conditions with severe risk of COVID-19 disease progression, and conditions with moderate risk of COVID-19 disease progression). To ensure comparability between groups, clinical activity among unexposed pregnancies will be required (with at most ± 14 days window) at the time of EVUSHELD injection in its matched EVUSHELD exposed pregnancy. Each pregnancy can only contribute to one exposure group within one analytic cohort. However, a pregnancy can be considered as unexposed in one analytic cohort and exposed in another analytic cohort.

Primary analyses

For categorical variables, frequency (number of cases, N) and percentage (%) of observations in each exposure group will be reported. For continuous variables, results will be presented as the mean with standard deviation (SD), and the median with interquartile range (IQR). The proportion of missing values for each variable will be reported.

For each analytic cohort, a descriptive analysis of baseline characteristics (ie, demographics, geography), pregnancy characteristics (ie, maternal age, gestational age), pregnancy history, laboratory tests, comorbidities, co-medications and substance abuse, and offspring characteristics will be conducted stratified by EVUSHELD exposure.

The risk with associated 95% confidence interval of each outcome (pregnancy and offspring outcomes) will be reported in pregnancies with EVUSHELD exposure and pregnancies without EVUSHELD exposure.

Secondary analyses

The EVUSHELD exposure characteristics (prior exposure, pregnancy period at first dose, time to second dose if applicable, cumulative dose, total number of doses, and total exposure duration) will be summarised descriptively in the exposure group.

In addition, pregnancy and offspring outcomes will be described among EVUSHELD-exposed pregnancies within strata of pregnancy characteristics.

Comparative exploratory analysis

Pending sufficient sample size requirements at the final analysis only, to address the exploratory objectives, comparisons of the outcomes of interest will be performed using Poisson regression models.

In each analytic cohort, PS matching will be used to control confounding. Each exposed pregnancy will be matched to one unexposed pregnancy using nearest-neighbour PS matching. Exposed pregnancies will only be matched to unexposed pregnancies within the same CEM set.

Modified Poisson regression models will be used to estimate risk ratios. Risk differences will be estimated by Poisson regression using an identity link with robust standard errors. Estimates will be reported alongside their 95% confidence intervals. Statistical significance for all comparative analyses is set at a test size (alpha) of 0.05. Analyses will use pregnancy as the statistical unit of analysis. Appropriate statistical tools will be implemented to address the fact that the same individual can contribute multiple pregnancies to the analytic cohort and to account for rare outcomes (Section 9.7).

Meta-analysis

Data from countries other than the US will be analysed by research partners and all the study results will be pooled using a meta-analysis. For the primary analysis, a pooled risk estimate with 95% confidence interval will be estimated for each outcome using a meta-analysis of risk from the database-specific risk results. For exploratory objectives, a meta-analysis of each database-specific estimate will be implemented and pooled risk ratio and risk difference with 95% confidence interval will be estimated for each outcome.

Milestones:

Refer to Section 12 for further information on content of each report.

Milestone	Planned date
Registration in the EU PAS register	Prior to the start of data collection
Start of data collection	01 April 2023
End of data collection (analytical dataset complete)	31 March 2027
Annual progress report 1	30 June 2023
Interim report 1	31 December 2023
Annual progress report 2	30 June 2024
Interim report 2	31 December 2024
Interim report 3	31 December 2025
Interim report 4	31 December 2026
Final study report	31 December 2027

5 AMENDMENTS AND UPDATES

Table 1 Amendments and Updates

Number	Date	Section of study protocol	Amendment or update	Reason
Not applicable	Not applicable	Not applicable	None	Not applicable

6 MILESTONES

Table 2 Study Milestones

Milestone	Planned date
Registration in the EU PAS register	Prior to the start of data collection
Start of data collection (data extraction start date)	01 April 2023
End of data collection (analytical dataset complete)	31 March 2027
Annual progress report 1	30 June 2023
Interim report 1	31 December 2023
Annual progress report 2	30 June 2024
Interim report 2	31 December 2024
Interim report 3	31 December 2025
Interim report 4	31 December 2026
Final study report	31 December 2027

7 RATIONALE AND BACKGROUND

Despite the wide use of over 11 billion doses of Coronavirus disease 2019 (COVID-19) vaccines, certain populations do not achieve sufficient immune response or are ineligible to receive the COVID-19 vaccine (1). These populations are at risk for serious adverse outcomes related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (2–9). This includes individuals at high risk for adverse reactions to a COVID-19 vaccine, individuals at high risk for mounting an insufficient immune response following vaccination and/or individuals at high risk for serious sequelae from SARS-CoV-2 infection. As an alternative or in addition to COVID-19 vaccination, COVID-19 pre-exposure prophylaxis with monoclonal antibody therapy can protect against COVID-19-related morbidity and mortality in such high-risk populations.

EVUSHELD™ (tixagevimab, cilgavimab) is a long-acting monoclonal antibody combination therapy for prevention of COVID-19. EVUSHELD received emergency use authorisation (EUA) in the United States of America (US) on 8 December 2021 as pre-exposure prophylaxis against COVID-19 in individuals 12 years of age and older weighing at least 40 kilograms (kg). It is now authorised in various regions across the globe and notably in the European Union (EU). EVUSHELD is given in 2 separate consecutive intramuscular injections in immediate succession, one of tixagevimab and one of cilgavimab. Dosing can be repeated every 6 months or more frequently, depending on country-specific recommendations (refer to Annex 3 for EVUSHELD dosing recommendations) (10,11). In the US, EVUSHELD is indicated for those without an active infection of SARS-CoV-2 and who also have a history of severe adverse reactions to a COVID-19 vaccine or have moderate-to-severe immunocompromising conditions coupled with a risk of not mounting an appropriate immune response to COVID-19 vaccination (10). In other countries, EVUSHELD may be administered in populations ineligible for COVID-19 vaccine with conditions that place them at higher risk for severe COVID-19 illness such as diabetes, obesity, or respiratory disease (12,13).

While other SARS-CoV-2 monoclonal antibody therapies have received EUA in the US (ie, casirivimab/imdevimab, bebtelovimab, bamlanivimab/etesevimab, and sotrovimab), or interim order authorised with terms and conditions in Canada (ie, casirivimab/imdevimab, bamlanivimab/etesevimab, and sotrovimab), or marketing authorisation in the EU (ie, casirivimab/imdevimab, and sotrovimab) for treatment of COVID-19 (14–17), EVUSHELD remains the only monoclonal antibody authorised for pre-exposure prophylaxis against COVID-19 to date.

For ethical reasons, pregnant women were excluded from EVUSHELD clinical studies and therefore, there are no clinical trial data on the safety of EVUSHELD in pregnant individuals (18). Following authorisation, EVUSHELD may be used intentionally by individuals with high-risk conditions (including but not limited to cancer, solid organ transplant, human immunodeficiency virus/acquired immune deficiency syndrome [HIV/AIDS], prolonged systemic corticosteroid use, immunodeficiencies, autoimmune conditions and immune-mediated inflammatory disorders; refer to Section 9.2.2) (19), during pregnancy as pre-exposure prophylaxis to minimise the known COVID-19-related risks of adverse pregnancy outcomes, such as preeclampsia, maternal death, preterm birth, low birth weight, and stillbirth (20–25). Additionally, unintended EVUSHELD exposure during pregnancy may occur if EVUSHELD is received as pre-exposure prophylaxis for other predisposing conditions before knowledge of a pregnancy (including the preconception period). For these reasons, it is imperative to fully understand the safety profile associated with EVUSHELD exposure during pregnancy as post-authorisation data become available internationally.

This non-interventional multi-country cohort study or post-authorisation safety study (PASS) in pregnancy has been designed to fulfil EVUSHELD's pharmacovigilance plan as specified in the EVUSHELD Core Risk Management Plan, and notably in the additional pharmacovigilance activities in the EVUSHELD EU RMP (18).

8 RESEARCH QUESTION AND OBJECTIVES

8.1 Research Question

What are the pregnancy and offspring (neonatal and infant) outcomes following EVUSHELD exposure among pregnancies in women of child-bearing potential eligible for EVUSHELD treatment?

8.2 Primary Objectives

The primary objectives of this study are to:

- 1 Describe the risk of pregnancy outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies. Outcomes of interest include: spontaneous abortion, pre-eclampsia, ectopic pregnancy, maternal death, gestational diabetes, gestational hypertension, preterm live birth, stillbirth.
- 2 Describe the risk of offspring outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies.
 - (a) Neonatal outcomes of interest include: low birth weight, small for gestational age (SGA), respiratory distress syndrome in the newborn, neonatal death.
 - (b) Infant outcomes of interest include: major congenital malformations, infant death, and failure to thrive.

8.3 Secondary Objectives

The secondary objectives of this study are to:

- 1 Describe EVUSHELD utilisation patterns, including number of doses, cumulative dose, and duration of treatment, among EVUSHELD-exposed pregnancies
- 2 Describe the risk of the pregnancy and offspring outcomes listed above among EVUSHELD-exposed pregnancies within strata of individual and pregnancy characteristics including:
 - (a) Maternal age
 - (b) High-risk condition type (severely immunocompromised persons, risk of severe COVID-19 progression, risk of less severe COVID-19 progression)
 - (c) Trimester of index date
 - (d) Recent SARS-COV-2 infection

- (e) Timing of last SARS-COV-2 vaccination relative to gestation
- (f) Other SARS-COV-2 monoclonal antibody

8.4 Exploratory Objectives

Pending sufficient sample size requirements at the final analysis only, the exploratory objectives of this study are to estimate the risk ratios and risk differences between exposed and matched unexposed pregnancies:

- 1 Compare the risk of pregnancy outcomes in matched EVUSHELD-exposed and unexposed pregnancies. Outcomes of interest include: spontaneous abortion, preterm live birth, ectopic pregnancy, maternal death, and stillbirth.
- 2 Compare the risk of offspring outcomes in matched EVUSHELD-exposed and unexposed pregnancies.
 - (a) Neonatal outcomes of interest include: neonatal death and SGA.
 - (b) Infant outcome of interest includes major congenital malformations.

9 RESEARCH METHODS

9.1 Study Design

9.1.1 Overview

This is a multi-country, non-interventional cohort study conducted within secondary data sources (administrative claims, electronic medical records (EMR) and/or registry data) from the following proposed countries: Canada, France, and the US. For each country, the overall study period will span 12 months prior to the country-specific EVUSHELD availability until the end of the data cut or 31 March 2027, whichever is earlier. The study will include pregnancies in females aged 18 to 49 years having a high-risk condition (eligible for EVUSHELD therapy) documented in the 12 months prior to the start of the pregnancy, defined as the first day of the last menstrual period (LMP).

The acronym LMP will be used to denote the first day of the last menstrual period throughout the remainder of this document. Pregnancy is the unit of analysis, and a single individual can contribute more than one pregnancy to an analytic cohort. A pregnancy is considered exposed to EVUSHELD if 1 of 2 conditions are met: (1) EVUSHELD was received during the 36-week period prior to LMP (ie, pre-pregnancy period), or (2) EVUSHELD was received on/after LMP during the exposure ascertainment period, which will vary based on the outcome of interest. Pregnancies exposed to EVUSHELD prior to the pre-pregnancy period are eligible for the study. The 36-week pre-pregnancy period reflects the amount of time EVUSHELD is detectable in serum following administration (26), and corresponds to around

3 half-lives of EVUSHELD (extended half-life ranging 83-88 days depending on component (27)).

The assessment of each outcome will involve creating distinct analytic cohorts whose design is tailored to the aspects of the outcome, such as the timeframe of its ascertainment, the etiologically relevant exposure window, and relevant gestational age. To facilitate characterisation of outcomes in comparable groups, each analytic cohort consists of EVUSHELD-exposed pregnancies that are matched to unexposed pregnancies for contextualisation purposes (see Section 9.7.1 for details on matching procedures). For the exploratory comparative analyses, risk ratios and risk differences will be estimated; pending sufficient sample size requirements at the final analysis only. Details for each of these tailored analytic cohorts are provided in the next section. Table 3 summarises the analytic cohort design for each outcome, including the index date and periods for exposure, outcome, and confounder ascertainment.

If appropriate, considerations on the current study design will be presented in the study progress reports based on information on pregnant patient counts with key baseline characteristics, product uptake, distribution of high-risk conditions and high-risk groups among EVUSHELD-exposed and unexposed pregnancies.

9.1.2 Time Periods and Index Date

Where specified below, the time periods for each analytic cohort are country-specific. In Canada, data from province-specific sources will be analysed and it will not be possible to obtain results for the entire country.

Overall study period: The time frame spanning 12 months prior to the country-specific EVUSHELD availability date until the end of the data cut or 31 March 2027, whichever is earlier. This timeframe is defined separately for each country.

The time periods, LMP date, and index date reflected in each analytic cohort design are defined as follows:

Last Menstrual Period (LMP) Definition: LMP is established by subtracting the estimated gestational age from the date of the end of pregnancy. When gestational age is not available at birth, it is obtained from gestational age codes from the mother and offspring medical or claims records within 30 days after the end of pregnancy episode. Gestational age codes are specific to the timing of each pregnancy ending event and are specified in Annex 1 (28,29).

LMP eligibility period: The timeframe in which all pregnancies eligible for inclusion in the analytic cohort are identified. This timeframe is defined separately for each country and each outcome type (and in some cases, for an outcome within an outcome type) to ensure the maximum number of pregnancies are included in the analysis.

Exposure ascertainment period: The timeframe in which EVUSHELD exposure is identified to determine whether a pregnancy is categorised as exposed or unexposed. This timeframe is defined separately for each outcome type (and in some cases, for a specific outcome within an outcome type) to ensure exposure capture is etiologically relevant to the outcome.

Index date: For an EVUSHELD-exposed pregnancy, the index date reflects the first date of EVUSHELD exposure during the exposure ascertainment period. If EVUSHELD was received on/after the first day during the exposure ascertainment period, the index date is the date of EVUSHELD receipt. If EVUSHELD was received any time from the 36th week prior to LMP until the start of the exposure ascertainment period, the index date will be the first day of the exposure ascertainment period (Note: Pregnancies with EVUSHELD exposure within 36 weeks prior to LMP are included in the exposed group, because the long half-life of EVUSHELD is such that drug received during this timeframe will still be pharmacologically active when the pregnancy begins, thus potentially increasing outcome risk).

To ensure comparability between groups, clinical activity among unexposed pregnancies is required (with at most ± 14 days window) at the time of EVUSHELD injection in its matched EVUSHELD exposed pregnancy. For an unexposed pregnancy, the index date is the clinical activity date (ie, the date of any healthcare encounter, or LMP when the index date for the exposed pregnancy is LMP, or 20th week gestation when the index date for the exposed pregnancy is the 20th week gestation for those outcomes studies from this period) within, at most, 14 days of the index date of its matched EVUSHELD exposed pregnancy when EVUSHELD injection occurs from the first day of the exposure ascertainment period. When EVUSHELD injection occurs before the first day of the exposure ascertainment period (ie, the index date is LMP, or the 20th week gestation for those outcomes studied from this period), a clinical activity in the unexposed pregnancy within, at most, 14 days of EVUSHELD injection is necessary to be selected.

Confounder ascertainment period (baseline period): The timeframe in which the values of potential confounders for a given pregnancy are identified. For pregnancy outcomes, this timeframe is from the 12 months prior to LMP until the index date. The length of this timeframe will be longer than 12 months to the extent that index date takes place after LMP (ie, first EVUSHELD exposure during the exposure ascertainment period is after LMP). For offspring outcomes, this timeframe is from the 12 months prior to the LMP until the date of birth. For the analysis of major congenital malformations, teratogenic medication exposure will be assessed only during the first trimester.

Outcome ascertainment period: The timeframe in which occurrence of outcome can be identified to determine whether a pregnancy is categorised as having had the outcome or not having had the outcome. This timeframe is defined separately for each outcome type (and in

some cases, for an outcome within an outcome type), as per the Global Alignment of Immunisation Safety Assessment in Pregnancy (GAIA) and Brighton Collaboration (30,31).

Follow-up period: For pregnancy outcomes, the time at risk will be defined as the time between the index date to the earliest occurrence of the outcome, end of the outcome ascertainment period, end of data, end of enrolment or clinical activity, maternal death (if applicable), or other SARS-CoV-2 monoclonal antibody administration. For offspring outcomes, the time at risk will be defined as the time between index date to the earliest occurrence of the outcome, end of the outcome ascertainment period, end of data, end of enrolment or clinical activity, or offspring death (if applicable).

Table 3 Summary of Outcome-specific Analytic Cohorts

Outcome Type	Outcomes Included	Eligible Pregnancies	LMP eligibility period	Exposure Ascertainment Period	Index Date	Confounder Ascertainment Period (Baseline Period)	Outcome Ascertainment Period
Pregnancy Outcomes							
Pregnancy outcomes potentially associated with exposure in early pregnancy and measured prior to 20 weeks gestation	Spontaneous abortion, Ectopic pregnancy	All pregnancies	Earliest possible LMP date: Country-specific EVUSHELD availability* Latest possible LMP date: 20 weeks (aligned to gestation) prior to the end of the study period	LMP date to < 20 weeks of gestation (Based on EVUSHELD exposure occurring within the 36 weeks prior to LMP or from LMP until the 20th week of pregnancy)	Exposed: First date of EVUSHELD exposure during the exposure ascertainment period Unexposed: Clinical activity date (or LMP when the index date for the exposed pregnancy is LMP) within, at most, 14 days of matched EVUSHELD exposed pregnancy index date	12 months prior to LMP until index date Note: The length of this period will be longer than 12 months to the extent that index date takes place after LMP.	Index date to < 20 weeks of gestation
Pregnancy outcomes potentially associated with exposure anytime during	Maternal death	All pregnancies	Earliest possible LMP date: Country-specific EVUSHELD availability*	LMP date to end of pregnancy (Based on EVUSHELD exposure occurring	Exposed: First date of EVUSHELD exposure during the exposure ascertainment period	12 months prior to LMP until index date Note: The length of this period will be	Index date to end of pregnancy Note: Maternal death outcome ascertainment period

Table 3 Summary of Outcome-specific Analytic Cohorts

Outcome Type	Outcomes Included	Eligible Pregnancies	LMP eligibility period	Exposure Ascertainment Period	Index Date	Confounder Ascertainment Period (Baseline Period)	Outcome Ascertainment Period
pregnancy and measured anytime during pregnancy			Latest possible LMP date: 45 weeks (aligned to gestation) plus 42 days prior to the end of the study period	within the 36 weeks prior to LMP or from LMP until the end of pregnancy)	Unexposed: Clinical activity date (or LMP when the index date for the exposed pregnancy is LMP) within, at most, 14 days of matched EVUSHELD exposed pregnancy index date	longer than 12 months to the extent that index date takes place after LMP.	is up to 42 days after the end of pregnancy episode (EPE).
Pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured after 20 weeks gestation	Preterm live birth, Stillbirth, Gestational hypertension, Pre-eclampsia, Gestational diabetes Note: Live birth is not included as an outcome of interest since it represents the complement of stillbirth	Pregnancies with gestational age of 20+ weeks Note: For preterm live births, only live births are eligible pregnancies	Earliest possible LMP date: Country-specific EVUSHELD availability* Latest possible LMP date: 45 weeks (aligned to gestation) prior to the end of the study period Note: for preterm birth, the latest possible LMP date is 37 weeks (aligned to gestation) prior to the end of the study period.	20th week gestation to end of pregnancy (Based on EVUSHELD exposure occurring within 36th week prior to LMP until the 20th week gestation or from the 20th week gestation until the end of pregnancy)	Exposed: First date of EVUSHELD during the exposure ascertainment period Unexposed: Clinical activity date (or 20th week gestation when the index date for the exposed pregnancy is the 20th week gestation) within, at most, 14 days of matched EVUSHELD exposed pregnancy index date	12 months prior to LMP until index date Note: The length of this period will be longer than 12 months to the extent that index date takes place after LMP.	Index date to end of pregnancy Note: For preterm birth, the outcome ascertainment period is 20 to 37 weeks of gestation

Table 3 Summary of Outcome-specific Analytic Cohorts

Outcome Type	Outcomes Included	Eligible Pregnancies	LMP eligibility period	Exposure Ascertainment Period	Index Date	Confounder Ascertainment Period (Baseline Period)	Outcome Ascertainment Period
Neonate Outcomes							
Outcomes in neonates potentially associated with exposure anytime during pregnancy and measured 28 days after birth	Low birth weight, Small for gestational age (SGA), Respiratory distress syndrome in the newborn, Neonatal death	Pregnancies ending in live births with linked infant data	Earliest possible LMP date: Country-specific EVUSHELD availability* Latest possible LMP date: 45 weeks (aligned to gestation) plus 28 days (aligned to follow-up) prior to the end of the study period. Note: For low birth weight, the latest possible LMP date is 45 weeks (aligned to gestation) plus 7 days (aligned to follow-up) prior to the end of the study period. For SGA, the latest possible LMP date is 45 weeks (aligned to gestation) plus 7 days (aligned to follow-up) prior to the end of the study period.	Date of birth (Based on maternal exposure status during LMP to end of pregnancy)	Date of birth	12 months prior to LMP until the date of birth	Date of birth up to 28 days of age Note: the outcome ascertainment window for low birth weight and SGA is up to 7 days after the date of birth for LBW, and 30 days for SGA to account for the delay of capture in claims data

Table 3 Summary of Outcome-specific Analytic Cohorts

Outcome Type	Outcomes Included	Eligible Pregnancies	LMP eligibility period	Exposure Ascertainment Period	Index Date	Confounder Ascertainment Period (Baseline Period)	Outcome Ascertainment Period
Infant Outcomes							
Outcomes in infants potentially associated with exposure anytime during pregnancy and measured within 12 months after birth	Major congenital malformations, Infant death, Failure to thrive	Pregnancies ending in live births with linked infant data	Earliest possible LMP date: Country-specific EVUSHELD availability* Latest possible LMP date: 41 6/7 weeks (aligned to gestation) plus 12 months (aligned to follow-up) prior to the end of the study period	Date of birth (Based on maternal exposure status during LMP to end of pregnancy)	Date of birth	12 months prior to LMP until the date of birth Note: For the analysis of major congenital malformations, teratogenic medication exposure will be assessed only during the first trimester.	Date of birth up to 12 months of age

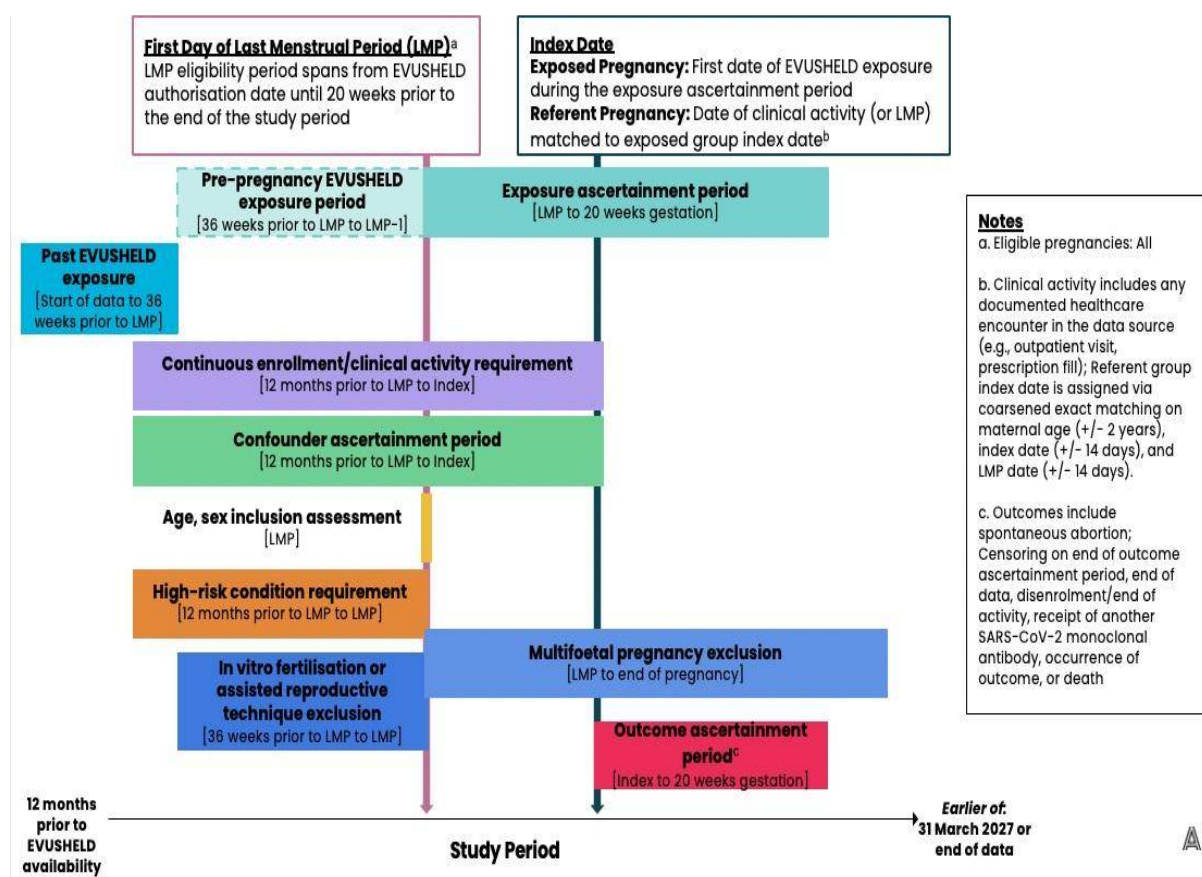
Note: LMP=First day of last menstrual period; LMP is synonymous with the start of a given pregnancy episode

* EVUSHELD authorisation/EUA/early access dates: Canada: 14 April 2022; France: 14 January 2022; US: 8 December 2021.

Visual representations of outcome-specific analytic cohort designs are presented for selected outcome types below in [Figure 1](#) and [Figure 5](#) for further illustration purposes.

[Figure 1](#) depicts study design elements and time periods for pregnancy outcomes potentially associated with exposure in early pregnancy (ie, spontaneous abortion). In this scenario, first EVUSHELD exposure in the exposed pregnancy occurs after LMP but before the 20th week of gestation.

Figure 1 Analytic Cohort Design for Pregnancy Outcomes Potentially Associated with Exposure in Early Pregnancy (depicts a hypothetical pregnancy with first EVUSHELD exposure after LMP and before 20th week gestation)



[Figure 2](#), [Figure 3](#), and [Figure 4](#) present modified versions of [Figure 1](#) to visualise the index date and how study time periods change for the evaluation of the spontaneous abortion outcome depending on the timing of the first EVUSHELD dose relative to LMP and the exposure ascertainment window.

[Figure 2](#) depicts study design elements and time periods for a hypothetical pregnancy receiving EVUSHELD at 6 weeks of gestation and included in the analytical cohort for

spontaneous abortion. In this scenario, this pregnancy is considered exposed (as the exposure ascertainment period starts at LMP and ends at 20 weeks of gestation) and the index date corresponds to the start of the 6th week of gestation, being the first day of EVUSHELD exposure during the exposure ascertainment period.

Figure 2 Analytic Cohort for Spontaneous Abortion: Pregnancy Exposed to EVUSHELD 6 Weeks of Gestation (ie, during the exposure ascertainment period)

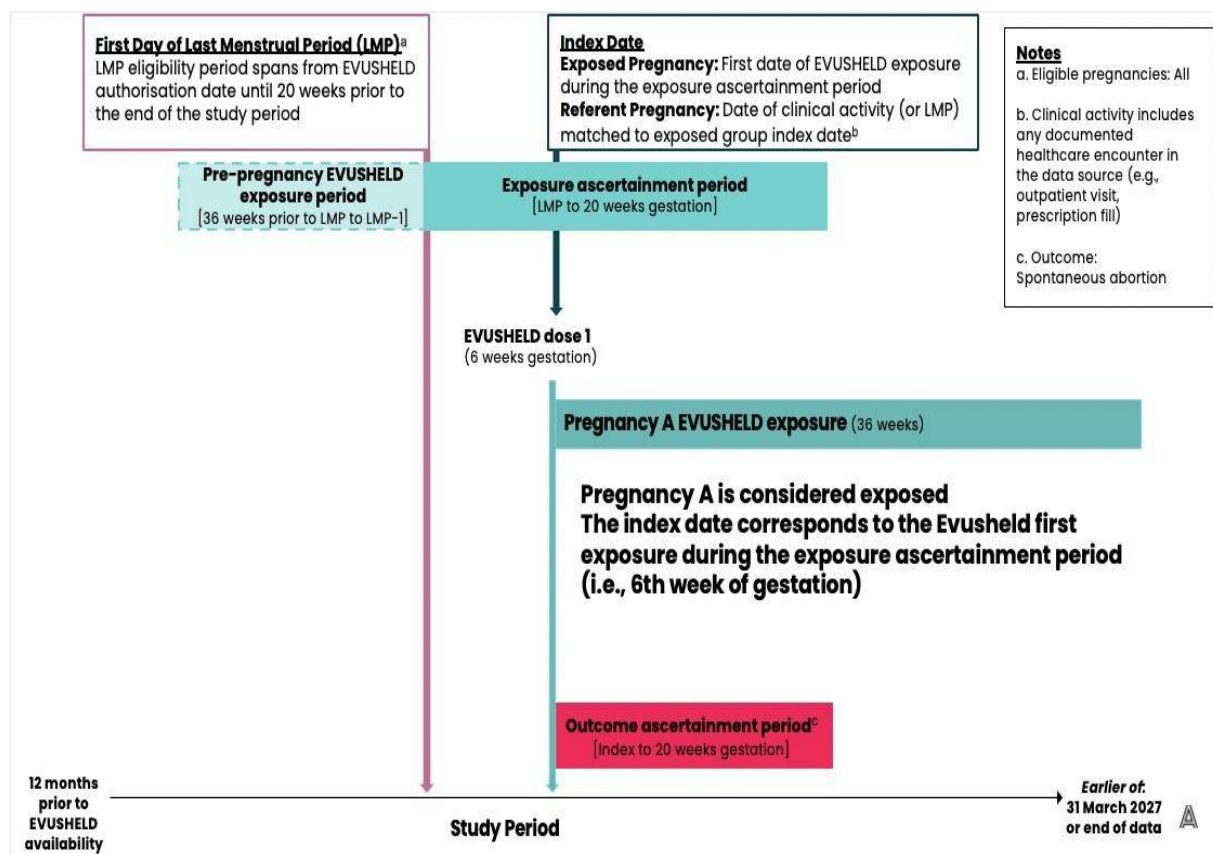


Figure 3 depicts study design elements and time periods for a hypothetical pregnancy receiving EVUSHELD at 21 weeks of gestation and included in the analytical cohort for spontaneous abortion. In this scenario, the first EVUSHELD exposure falls just after the end of the exposure ascertainment window. Therefore, this pregnancy could be selected as a referent pregnancy for the spontaneous abortion outcome.

Figure 3 **Analytic Cohort for Spontaneous Abortion: Pregnancy Exposed to EVUSHELD 21 Weeks of Gestation (ie, after the exposure ascertainment period)**

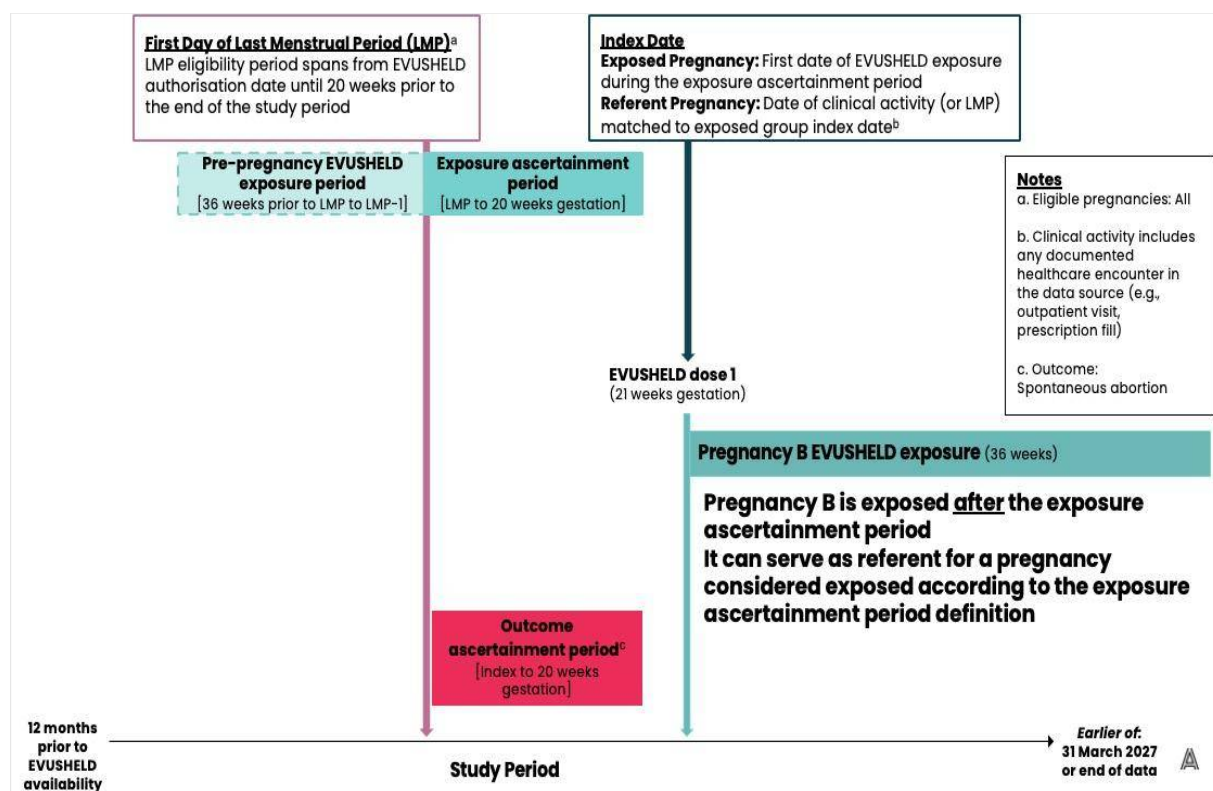


Figure 4 depicts study design elements and time periods for a hypothetical pregnancy receiving EVUSHELD 6 weeks prior LMP and included in the analytical cohort for spontaneous abortion. In this scenario, this pregnancy is considered exposed and the index date corresponds to the LMP (eg, first day of EVUSHELD exposure during the exposure ascertainment period), being the first exposure during the exposure ascertainment period.

Figure 4 Analytic Cohort for Spontaneous Abortion: Pregnancy Exposed to EVUSHELD Prior to LMP and During the Exposure Ascertainment Period

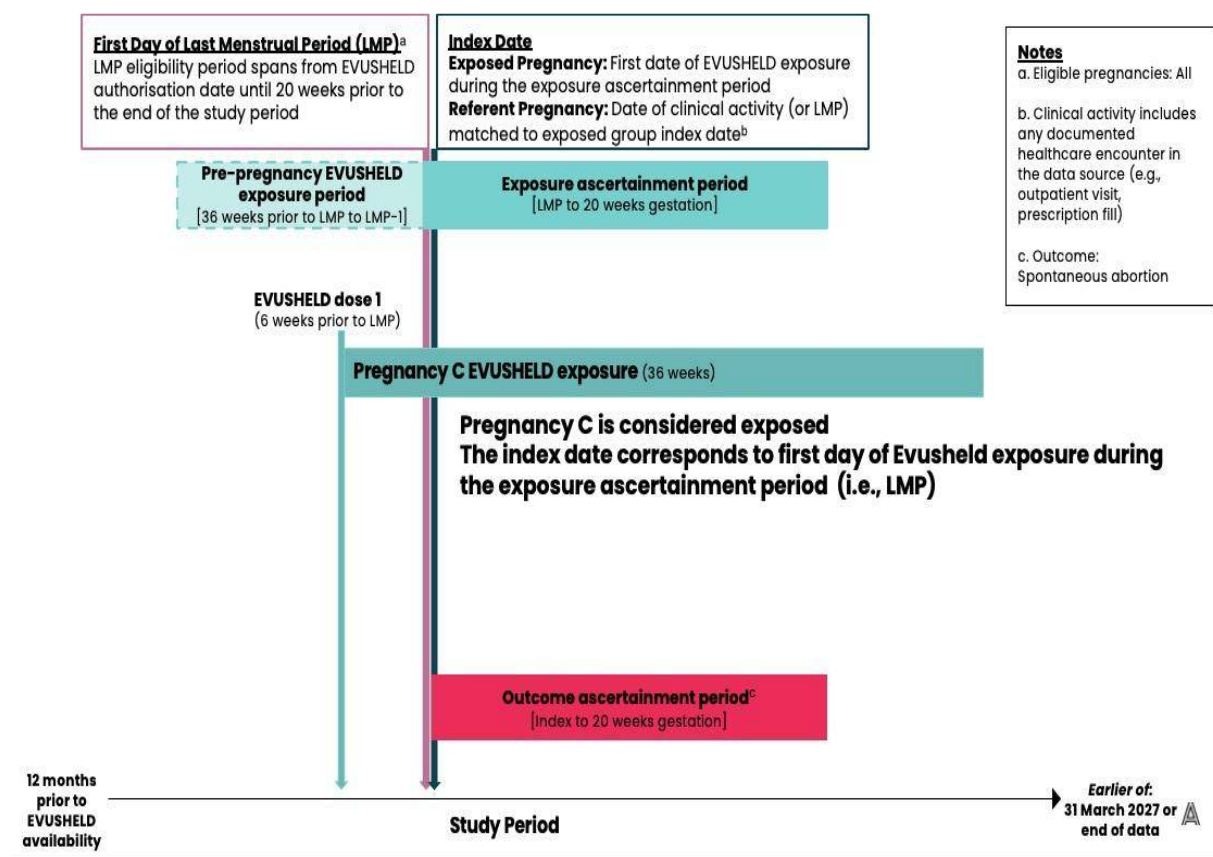
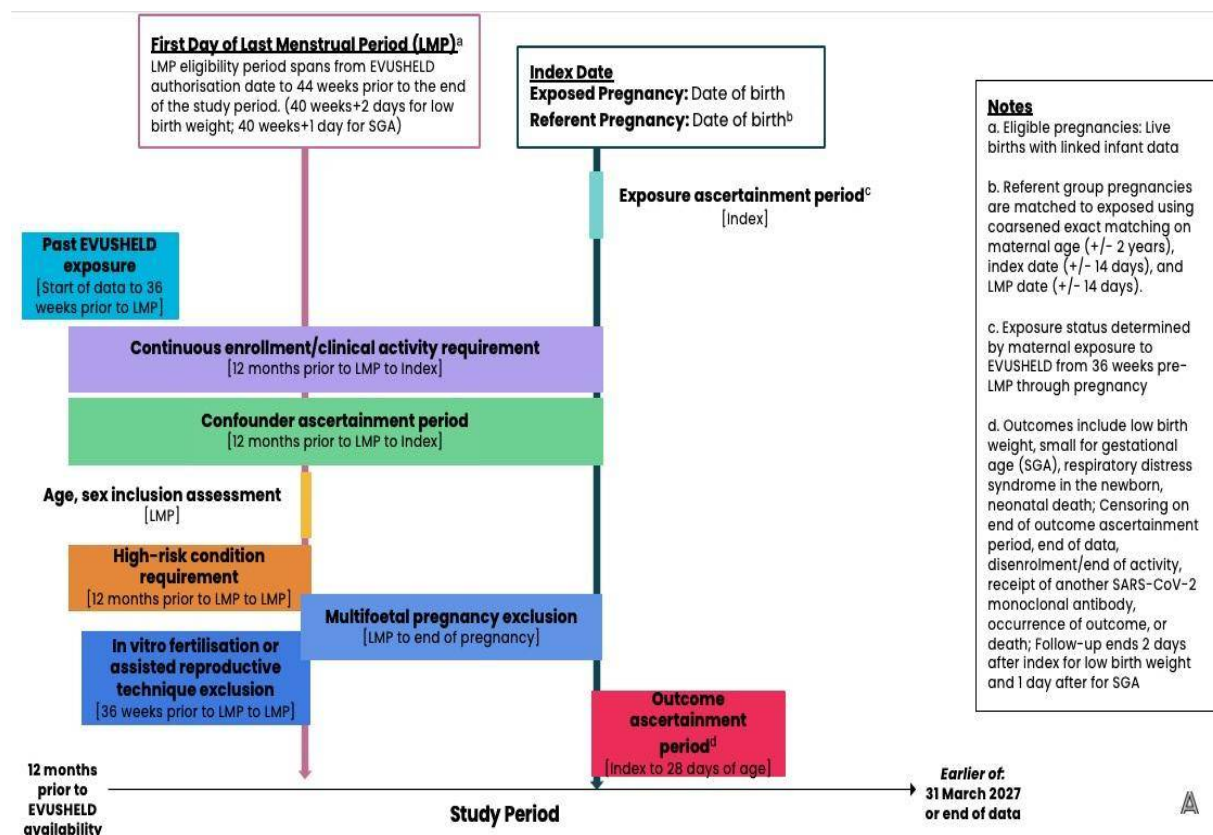


Figure 5 provides an example of the design for post-birth outcomes, specifically for analysis of neonatal outcomes.

Figure 5 Analytic Cohort Design for Neonatal Outcomes



Analytic cohort-specific study design figures for other outcome types are provided in the [Appendix C](#), including pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured anytime during pregnancy, pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured after 20 weeks gestation, and offspring outcomes.

9.2 Setting

9.2.1 Population

The study will include pregnancies in individuals eligible for EVUSHELD therapy in each country, including pregnant females aged 18-49 years with a high-risk condition. Exposed and unexposed pregnancies will be identified from this population for outcome-specific analyses. EVUSHELD indication varies from one country to another and may evolve over the course of the study. In order to have a homogeneous study population and maximise its size, all country-specific EVUSHELD eligibility criteria at the time of protocol development were considered to define the study population.

9.2.2 Inclusion Criteria

Pregnancies (including start and end dates) will be identified via an algorithmic approach which relies on diagnosis and/or procedure codes to identify pregnancy outcomes (eg, live birth, stillbirth, spontaneous abortion). Published algorithms validated for use in the US and French claims databases, and Canadian pregnancy cohorts will be considered (32–34). The chosen algorithmic approach in each country will be further described in the Statistical Analysis Plan (SAP).

Pregnancies meeting the following criteria will be eligible to be included within each analytic cohort as defined in [Table 3](#):

- Female sex at LMP
- Age 18-49 years at LMP
- Continuous coverage/clinical activity (dependent on data source type) within the confounder ascertainment period, as defined in [Table 3](#)
- LMP date falls within the LMP eligibility period, as defined [Table 3](#)
- Occurrence of at least one of the following high-risk conditions during the confounder ascertainment period (10,11,15) (for detailed list of high-risk conditions with codes, refer to Annex 1)
 - Immunocompromised conditions:
 - Cancer (active solid cancer, blood cancer, or receipt of chemotherapy, immunotherapy, or radiotherapy)
 - Solid organ transplant
 - HIV/AIDS
 - Prolonged systemic corticosteroid use (15–20 mg of prednisone equivalents for greater than 2 weeks)
 - Receipt of T or B cell depleting therapy, anti-Tumour Necrosis Factor (anti-TNF), or other immunosuppressive agents
 - Receipt of stem cell transplant
 - Receipt of gene cell therapy of the CAR-T cell type
 - Congenital immunodeficiency, primary immune deficiencies (treatment with subcutaneous or intravenous immunoglobulins - and/or immunodeficiency diagnosis codes), severe or combined immunodeficiency (including transplanted Severe combined immunodeficiency [SCID] where immunoglobulin replacement is required)
 - Other autoimmune conditions and immune-mediated inflammatory disorders (such as systemic lupus erythematosus, Crohn's disease, ulcerative colitis). The full list of disorders can be found in Annex 1

- Conditions that increase risk of COVID-19 disease progression (2–9,35)
 - Severe risk of COVID-19 disease progression: sickle cell disease, chronic lung disease (ie, chronic bronchitis, Chronic obstructive pulmonary disease [COPD], cystic fibrosis, emphysema with dyspnoea on exertion), chronic kidney disease, cardiovascular diseases (ie, heart failure, coronary artery disease, cardiomyopathies), moderate to severe asthma, Down syndrome, rare neurological conditions (ie, multiple sclerosis, motor neurone disease, myasthenia gravis, Huntington’s disease), gestational diabetes requiring medication
 - Moderate risk of COVID-19 disease progression: type I or II diabetes, obesity, chronic liver disease, congenital heart disease

9.2.3 Exclusion Criteria

Pregnancies meeting at least one of the following criteria will be excluded from each analytic cohort as defined in [Table 3](#):

- Multifoetal pregnancies are defined by the presence of any International Classification of Diseases (ICD-10) diagnosis code, any position indicating presence of more than one foetus (see code list) on the hospital record throughout the pregnancy episode (28,32)
- Use of in vitro fertilisation or other assisted reproductive technology in the 36 weeks prior LMP as identified by ICD-10 diagnosis code “pregnancy resulting from assisted reproductive technology” or related procedure codes indicating in vitro fertilisation (IVF) or assisted reproductive technology (ART) (see code list) on the electronic health records (EHR) or hospital claims records 36 weeks prior to LMP (36,37)

9.2.4 Subgroups

The following subgroups will be considered for the secondary objective of stratified descriptive analyses of pregnancy, offspring outcomes among exposed pregnancies:

- Age subgroups: ≤ 20 , 21-34, 35-40, ≥ 41 years
- High-risk condition subgroups (refer to Section [9.2.2](#) for list of conditions and Annex 1 for detailed list with codes)
 - Immunocompromised or immunodeficient
 - Severe increased risk for COVID-19 disease progression
 - Less severe increased risk for COVID-19 disease progression
- Trimester of index date
- Recent SARS-COV-2 infection (yes/no): in the <30 days prior to any EVUSHELD exposure during the confounder ascertainment period
- Timing of last SARS-COV-2 vaccination relative to gestation in 3-month increments

- Other SARS-COV-2 monoclonal antibody users

9.3 Variables

The operational definitions of the analytic variables for the entry criteria, exposure, outcomes, potential confounders, and subgroups are described below. These operational definitions are based on diagnosis and procedures coded with ICD-10 codes (or ICD-9 mapped), Healthcare Common Procedure Coding System (HCPCS), National Drug Codes (NDC), generic drug names, lab values (when available) and corresponding Anatomical Therapeutic Chemical (ATC) codes.

9.3.1 Exposure

A pregnancy is considered exposed to EVUSHELD if 1 of 2 conditions are met: (1) EVUSHELD was received during the 36-week period prior to LMP, or (2) EVUSHELD was received on/after LMP during the exposure ascertainment period.

For all pregnancy outcomes except for preterm live birth and stillbirth, the index date is defined as follows:

- If EVUSHELD was received during the 36-week period prior to LMP, the index date is LMP.
- If EVUSHELD was not received during the 36-week period prior to LMP and was received on/after LMP during the exposure ascertainment period, the index date is the date of EVUSHELD receipt.

For the outcomes of preterm live birth and stillbirth, the index date (the date of first EVUSHELD exposure within the exposure ascertainment period) is defined as follows:

- If EVUSHELD was received during the 36-week period prior to LMP or during the period from LMP to <20 weeks gestation, the index date is the first day of the 20th week gestation.
- If EVUSHELD was not received during the 36-week period prior to LMP or during the period from LMP to <20 weeks gestation and was received on/after the first day of the 20th week gestation during the exposure ascertainment period, the index date is the date of EVUSHELD receipt.

For the offspring outcomes, the offspring is considered exposed at index date (birth date) if EVUSHELD was received during the 36-week period prior to LMP or during the period from LMP to end of pregnancy (ie, based on maternal exposure status).

EVUSHELD administration will be captured via pharmacy claims and/or prescription information in EMR using ATC code J06BD03, non-proprietary name AZD7442, drug name tixagevimab and cilgavimab, US National Drug Code (NDC) code 0310-7442 or any other

appropriate local product code. EVUSHELD dosing recommendations by country are presented in Annex 3.

For the secondary objective of describing utilisation patterns among EVUSHELD-exposed pregnancies, variables for EVUSHELD exposure characteristics are operationally defined in [Table 4](#).

Table 4 EVUSHELD Treatment Characteristics

Variable	Operational Definition	Assessment Period
Past exposure	Categorical (yes/no) Exposure to EVUSHELD prior to pre-pregnancy exposure period	Any time prior to the pre-pregnancy exposure period (ie, before the 36 weeks prior LMP)
Prior exposure duration	Exposure duration starting from EVUSHELD injection during the pre-pregnancy period (36 weeks prior to LMP) until index date in days. <i>Example:</i> first dose is administered 34 weeks prior LMP and index date is one week after LMP then prior exposure duration is 35 weeks.	36 weeks prior LMP to index date
Pregnancy period at first dose	Categorical: pre-pregnancy, first trimester, second trimester, third trimester First exposure to EVUSHELD from 36 weeks prior to LMP until the end of pregnancy episode	36 weeks prior to LMP until the end of pregnancy episode
Exposed pregnancy period	Categorical: pre-pregnancy, first trimester, second trimester, third trimester Overall exposure to EVUSHELD from 36 weeks prior to LMP until the end of pregnancy episode (ie all doses administered during this period will be accounted for)	36 weeks prior to LMP until the end of pregnancy episode
Time to second dose (if applicable)	Time from first EVUSHELD dose to second EVUSHELD dose in days	36 weeks prior to LMP until the end of pregnancy episode
Cumulative dose	Cumulative dose of EVUSHELD (in mg) administered from index date until the end of pregnancy episode	36 weeks prior LMP until the end

Table 4 EVUSHELD Treatment Characteristics

Variable	Operational Definition	Assessment Period
		of pregnancy episode
Total number of doses	The count of doses administered. If EVUSHELD is given as 2 separate injections on the same day, this will account for 1 dose of EVUSHELD therapy	36 weeks prior LMP until the end of pregnancy episode
Total exposure duration	Exposure duration for one dose will span over a period of 36 weeks following the administration of the first dose. If another dose is administered before the exposure window expires, the exposure duration will be extended by another 36 weeks from that dose. Example: A second dose is administered 26 weeks after the first dose, the total exposure duration is 62 weeks (26+36).	36 weeks prior LMP until the end of pregnancy episode

9.3.2 Outcomes

Outcomes with corresponding operational definitions are listed in [Table 5](#). The operational definition of each outcome is based on validated algorithms from previous studies, where available, and determined appropriate specifically for use of secondary data. Where country variation exists for an outcome definition, a standardised definition is specified in the [Table 5](#) for the primary analyses. Country-specific definitions will be used in sensitivity analyses and will be detailed in the SAP.

The final list of outcomes that will be considered in this study are listed in [Table 5](#).

Table 5 Outcomes Operational Definitions

Outcome	Operational Definition* (refer to Annex 1 for code list)
Pregnancy / maternal outcomes	
Spontaneous abortion	ICD-10, CPT, or Healthcare Common Procedure Coding System (HCPCS) code indicating diagnosis of spontaneous abortion or related procedure (see code list) AND gestational age (GA) < 20 weeks (100.0% adjudication (95% CI 93.9–100.0) (32))
Preterm live birth	Gestational age at birth between 20th week and less than the 37th week of gestation AND ICD-10 diagnosis code or procedure code relating to a live birth (62.4% adjudication (95% CI 52.0–71.7) (32))

Table 5 Outcomes Operational Definitions

Outcome	Operational Definition* (refer to Annex 1 for code list)
Preeclampsia	Gestational age ≥ 20 weeks AND any ICD-10 diagnosis code of new onset (pregnancy-induced) hypertension AND new onset proteinuria (Specificity of 99.9% (38))
Ectopic Pregnancy	The first observed CPT or HCPCS procedure code in any position for extraction of end of pregnancy episode (EPE) AND within 2 weeks of another related code describing EPE (either EPE ICD-10 diagnosis code or pharmacy, prescription, or dispensing claim of either methotrexate or misoprostol) AND washout period of 56 days for all aforementioned codes (99–100% agreement (39,40))
Maternal Death	Date of recorded death
Stillbirth	GA > 20 weeks (country specific) AND ICD-10, CPT, or HCPCS code indicating stillbirth or related procedure (70.8% adjudication rate (32))
Gestational diabetes	No documented diagnosis any position of pre-gestational diabetes during the first trimester or 365 days before pregnancy AND either at least one diabetes mellitus code (O24.* or E11.*) on the delivery hospitalisation record OR at least 1 physician claim with a diabetes diagnosis code any position with a 90 day lookback before delivery (sensitivity of 95.9% (41))
Gestational hypertension	GA > 20 weeks AND Any ICD-10 diagnosis code any position of new onset (pregnancy-induced) hypertension (see code list) on hospital discharge record AND no diagnosis of new onset proteinuria in the previous gestational period of 20 weeks gestation (Sensitivity 82.36% (38))
Live Birth	GA > 20 weeks AND any ICD-10 diagnosis code identifying a live birth on the mothers' medical record (32) (see code list).
Neonatal outcomes	
Neonatal death	Date of recorded death within 28 days after live birth
Respiratory Distress Syndrome in the Newborn	ICD-10-CM diagnosis code of P22.0 respiratory distress syndrome of newborn-Hyaline membrane disease on the newborn medical record (no specificity reported (42))
Small for Gestational Age (SGA)	≥ 1 maternal or infant ICD-9-CM diagnostic code 656.5x, 764.0x, 764.1x, 764.9x recorded in inpatient or other therapy claims from delivery to delivery + 30 days (PPV 92% (95% CI, 82%-97%) (43))
Low Birth Weight (LBW)	First recorded new-born weight from the EHR is < 2500 g recorded within 24 hours of birth (PPV $> 80\%$ (44)) OR ICD-10 code on the infant record for LBW P07.0, P07.1
Infant outcomes	
Infant death	Date of recorded death in the 12 months after birth

Table 5 Outcomes Operational Definitions

Outcome	Operational Definition* (refer to Annex 1 for code list)
Failure to thrive	Any ICD-10 code for failure to thrive R62.8 or R62.9, or E34.3 (no specificity reported (45))
Major Congenital Malformations	An ICD-9 diagnosis code recorded for a specific malformation on the infant records on multiple dates OR a diagnosis was recorded as well as a relevant surgery or procedure code OR a diagnosis for a specific malformation recorded for one date and a record of infant death < 90 days (46,47) (see Annex 1 for major congenital malformations list with codes)

*Operational definitions are subject to local adaptations according to database-specific algorithms.

9.3.3 Covariates

The below section presents the list of covariates that will be assessed for each distinct analytic cohort across the pregnancy and offspring specific outcomes. The list of potential confounders for each comparative outcome of interest is also presented.

9.3.3.1 Pregnancy Variables

Table 6 presents the operational definition for pregnancy baseline and follow-up characteristics with corresponding period of assessment. These covariates will be used for descriptive analysis.

Table 6 Pregnancy Covariate Variables Definitions

Variable	Operational Definition* (refer to Annex 1 for code list)	Period of Assessment
Demographics		
Maternal Age	Continuous (in years) Categorical: ≤ 20 , 21-34, ≥ 35 years	Index date
Race (as available)	Categorical Adapted per country-specific race/ethnicity data availability (eg, not available in France). Example for the US: White, Asian, Black, Other, Unknown, or Missing.	Index date
Ethnicity (as available)	Categorical Adapted per country-specific race/ethnicity data availability (eg, not available in France). Example for the US: Not Hispanic, Hispanic, Unknown, or Missing	Index date
Health plan	Adapted per country-specific health plans. Example for the US: Commercial, Medicare, Medicaid, Other, Unknown	Index date

Table 6 Pregnancy Covariate Variables Definitions

Variable	Operational Definition* (refer to Annex 1 for code list)	Period of Assessment
Geography	Country (US, Canada, France)/ US region (Northeast, Southwest, West, Southeast, and Midwest)	Index date
Pregnancy characteristics		
Gestational Age at Index	Validated algorithm by Moll, 2021, using Z3A ICD-10-CM code indicating gestational age in weeks OR procedure codes to identify pregnancy outcomes (live births, stillbirths, spontaneous abortions, and ectopic pregnancies) (see code list) (32)	Index date
Care setting at delivery	Inpatient setting (>1 day duration) or outpatient setting (only 1 day duration with no other visit before or after) at pregnancy delivery.	End of pregnancy episode (EPE)
C-section delivery	C-section as recorded in EMR or any ICD-10 or CPT related procedure codes (see Annex 1 for code list)	EPE
Pregnancy history		
Prior pregnancy history (as available in EMR/claims)	Personal history of other complications of pregnancy, childbirth and the puerperium. The following outpatient or inpatient diagnosis (any position) at any time prior the pregnancy studied will be considered: spontaneous abortion, ectopic pregnancy, preterm birth, c-section, gestational diabetes, gestational hypertension, stillbirth.	Any time prior to LMP
Maternal parity (as available in EMR)	Number of times that a woman had given birth to a foetus with a gestational age of 24 weeks or more, regardless of whether the child was born alive or was stillborn (48). Parity will be collected from EMR or ICD-10 diagnosis code confirming a pregnancy end-point ≥ 24 weeks gestation.	Any time prior to LMP
Pre-pregnancy BMI	Last available BMI value prior to or at index date in EMR.	365 days prior to LMP
Comorbidities		
High-risk condition	At least one outpatient or inpatient diagnosis (any position) using claims or EMR of any of the following (please refer to Annex 1 for list of codes and detailed list of conditions): - Immunocompromised conditions: - active solid cancer or cancer treatment (chemo/immuno/radiotherapy), blood or bone marrow cancer - solid organ transplant - HIV/AIDS - high dose and prolonged use of corticosteroids (15–20 mg prednisone or equivalent for greater than 2–4 weeks)	365 days prior to LMP until index date

Table 6 Pregnancy Covariate Variables Definitions

Variable	Operational Definition* (refer to Annex 1 for code list)	Period of Assessment
	◦ received a T or B cell depleting therapy or anti-TNF or other immunosuppressive agents ◦ stem cell transplant recipients ◦ congenital immunodeficiency, primary immune disorders, severe or combined immunodeficiency (including transplanted SCID where immunoglobulin replacement is required) ◦ certain autoimmune conditions and immune-mediated inflammatory disorders • Conditions that increase risk of COVID-19 disease progression: ◦ <u>Risk of severe COVID-19 disease progression:</u> sickle cell disease, chronic obstructive pulmonary disease, chronic kidney disease, cardiovascular diseases (ie, heart failure, coronary artery disease, cardiomyopathies), moderate to severe asthma, down's syndrome, rare neurological conditions (ie, multiple sclerosis, motor neurone disease, myasthenia gravis, Huntington's disease) gestational diabetes requiring medication ◦ <u>Risk of less severe COVID-19 disease progression:</u> type I or II diabetes, obesity, chronic liver disease, congenital heart disease	
Other comorbidities	Any position outpatient or inpatient diagnosis of any of the following prior to pregnancy: epilepsy, chronic hypertension, thyroid disorders, mental health conditions, anaemia (49–60)	365 days prior to LMP until index date
Past Infections	Any ICD-10 code any position for at least one of the following infections: chlamydia (61)	365 days prior to LMP until index date
Active infection	Last result available from serology test for: Toxoplasma gondii, Treponema pallidum (syphilis), Rubella virus, Cytomegalovirus, Herpes simplex 1–2, Herpes virus 6, Varicella zoster, Hepatitis B and C virus, HIV, Parvovirus B19, trichomonas, gonorrhoea, malaria, Human papillomavirus (HPV), Lyme disease, Streptococcus B and non-polio Enteroviruses (55,56,62–64) OR ICD-10 related diagnosis codes on the mother record	LMP to EPE
SARS-CoV-2 infection	Any inpatient or outpatient diagnosis (any position) with ICD-10 code U07.1 (confirmed) OR Positive COVID-19 Nucleic Acid Amplification Test laboratory test	365 days prior to LMP until index date

Table 6 Pregnancy Covariate Variables Definitions

Variable	Operational Definition* (refer to Annex 1 for code list)	Period of Assessment
Co-medications and substance abuse		
Known teratogenic medications	At least one pharmacy claim or prescription of any known teratogenic medications (65) For complete list of medication please refer to Annex 1	First trimester
Substance use (tobacco, alcohol, illicit drugs)	Any outpatient or inpatient diagnosis (any position) related to tobacco/alcohol/drug/ use or dependency and related diagnosis. Please refer to Annex 1 for code list.	365 days prior to LMP until index date
Other SARS-CoV-2 monoclonal antibody	At least one pharmacy claim or prescription of another SARS-CoV-2 monoclonal antibody: asirivimab/imdevimab, bebtelovimab, bamlanivimab/etesevimab, and sotrovimab). Please refer to Annex 1 for code list. Note: The list of SARS-CoV-2 monoclonal antibodies will be re-evaluated during the conduct of the study as additional products may become available under (conditional) authorisation or Emergency Use Authorisation (EUA).	365 days prior to LMP until index date
Other COVID-19 therapies	Documented active (within 30 days of COVID-19 therapy administration) SARS-CoV-2 infection in the EMR or claims (as defined above) AND at least one pharmacy claim or prescription for treatment of COVID-19 including ritonavir, anakinra, regdanvimab, tocilizumab, casirivimab / imdevimab, remdesivir, sotrovimab. Note: The list of other COVID-19 therapies will be re-evaluated during the conduct of the study as additional products may become available under (conditional) authorisation or EUA.	365 days prior to LMP until index date
COVID-19 vaccination status	Any outpatient or inpatient encounter for COVID-19 immunisation OR pharmacy claim or prescription for COVID-19 vaccine administration with ATC code J07BX03.	365 days prior to LMP until index date

*Operational definitions are subject to local adaptations according to database-specific algorithms.

9.3.3.2 Offspring Variables

Table 7 presents operational definition for offspring covariates with corresponding period of assessment. These offspring covariates will be presented descriptively.

Table 7 Offspring Covariate Variables Definition

Offspring Covariates (birth to 1 year of age)		
Variable	Operational Definition* (refer to Annex 1 for code list)	Period of assessment
Sex	Categorical, as recorded in claims or EMR: Male or Female	At birth (index date)

Table 7 Offspring Covariate Variables Definition

Offspring Covariates (birth to 1 year of age)		
Variable	Operational Definition* (refer to Annex 1 for code list)	Period of assessment
Breastfed	Breastfeeding (yes/no) as reported in EMR as available	From birth to 12 months of age
Congenital infections	Refer to the list of active infections in Table 6 for laboratory test results OR ICD-10 related diagnosis codes on the mother or infants record	At birth (index date)
SARS-CoV-2 Infection	Any inpatient or outpatient diagnosis (any position) with ICD-10 code U07.1 (confirmed) OR Positive COVID-19 Nucleic Acid Amplification Test laboratory test	From birth to 12 months of age

*Operational definitions are subject to local adaptations according to database-specific algorithms.

9.3.3.3 Potential Confounding

Potential confounding variables considered for the exploratory comparative analyses are described in [Table 8](#) and [Table 9](#) for each outcome of interest. They have been selected based on targeted literature review for each outcome.

Table 8 List of Covariates for Each Pregnancy Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Pregnancy Outcomes of Interest for Comparative Analyses				
	Spontaneous abortion	Ectopic pregnancy	Preterm live birth	Stillbirth	Maternal death
Past EVUSHELD exposure	X	X	X	X	X
Prior EVUSHELD exposure duration	X	X	X	X	X
Demographics					
Maternal age	(50,66,67)	(68)	(60)	(55,56,69)	(57,70)
Race/ethnicity	(50,71)		(51,60)	(55,58)	(57,72)
Pregnancy History					
-previous spontaneous abortion	(50,66,71,73)				
- previous ectopic pregnancy		(66,68,74,75)			(66,75)
- previous preterm birth			(51,60)		
- nulliparity			(51)	(55,58)	(59,70)
Pre-pregnancy BMI	(50,71)		(60)	(55,56,58)	

Table 8 List of Covariates for Each Pregnancy Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Pregnancy Outcomes of Interest for Comparative Analyses				
	Spontaneous abortion	Ectopic pregnancy	Preterm live birth	Stillbirth	Maternal death
High-risk condition type (inclusion criteria)					
- pregestational diabetes	(66,76)		(51,54)	(55,58)	
- renal disease			(51)	(55)	(59)
-gestational diabetes requiring medication			(60)		(70)
-cardiovascular disease					(57,59)
Other comorbidities					
-thyroid disease	(50,66)			(55)	
-chronic hypertension			(51–54)	(57)	(57)
-mental health disorders	(66)			(58)	(59)
-anaemia			(60)	(55)	
Infections					
-chlamydia (current or hx) or gonorrhoea	(77,78)	(66,79)	(80)	(55,62)	(77)
-malaria, syphilis, HIV, Toxoplasmosis, rubella, Herpes 1-3 & 6, Cytomegalovirus, Hepatitis B	(62,64,81)		(62)	(55,56,62–64)	

Table 8 List of Covariates for Each Pregnancy Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Pregnancy Outcomes of Interest for Comparative Analyses				
	Spontaneous abortion	Ectopic pregnancy	Preterm live birth	Stillbirth	Maternal death
and C, Parvovirus B19, trichomonas, Human papillomavirus (HPV), Lyme disease, Streptococcus B and non-polio Enteroviruses					
SARS-CoV-2 infection			(82)	(82)	(21,22,82,83)
Co-Medications and Substance use					
Known teratogenic medications	(65,84)				
Substance use					
-alcohol consumption	(50,66,71,73)			(55,56)	(59)
-tobacco	(50,66,71)	(68,74,75,79)	(51,60)	(55,56,58,85)	
Other SARS-Cov-2 medication	X	X	X	X	X

Table 9 List of Covariates for Each Offspring Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Neonatal Outcomes		Infant Outcomes
	Neonatal death	SGA	Major Congenital Malformations
Past EVUSHELD exposure	X	X	X

Table 9 List of Covariates for Each Offspring Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Neonatal Outcomes		Infant Outcomes
	Neonatal death	SGA	Major Congenital Malformations
Prior EVUSHELD exposure duration	X	X	X
Breastfed	(86)		
Congenital infections	(62)	(62)	(62)
Maternal characteristics contributing to offspring outcomes			
Comorbidities			
- chronic hypertension	(53)	(53,87)	(88)
- epilepsy			(89)
Pre-pregnancy BMI	(90)	(87,91)	(92–95)
High-risk conditions			
- type I, type II, and gestational diabetes requiring medication		(87)	(93,94,96–99)
- gestational hypertension			(95,99,100)
Known teratogenic medications			(65,84,101,102)

Table 9 List of Covariates for Each Offspring Outcome of Interest in Exploratory Comparative Analyses

Covariates of Interest	Neonatal Outcomes		Infant Outcomes
	Neonatal death	SGA	Major Congenital Malformations
Substance use			
- tobacco	(85)	(87,91)	
- alcohol, illicit drugs			(94,103)
Race/ethnicity		(87,91)	(104)
Maternal Age		(87,91,105,106)	(94,107)
Parity		(87,105,106)	(108)

9.4 Data Sources

This study will use data from multiple existing secondary healthcare databases that each covers a large population and contains a mother-infant linkage. Data sources were selected after a feasibility assessment based on a structured process to identify fit-for-purpose data (SPIFD (109)). The feasibility included assessments on the data reliability, data relevance, and data access. Thus, ensuring high quality data on COVID-19 monoclonal antibodies (including EVUSHELD exposure), pregnancy and birth outcomes, and important covariates. A description of the feasibility and detailed findings are presented in Annex 2.

The following subsections include a brief description of each of the data sources. Each proposed research partner with access to patient-level data have indicated their interest in participating in the study.

9.4.1 Canada: Canadian Mother Child Cohort

The Canadian Mother Child Cohort (CaMCCo) is a population-based cohort capturing all pregnancies and births across 6 provinces in Canada (Alberta, British Columbia, Ontario, Québec, Manitoba, and Saskatchewan). Data is aggregated at a provincial level using a patient unique encrypted identifier to link multiple administrative and hospital databases with registries (pregnancy, birth, and death) within each region. The cohort is annually refreshed with a one-year data lag resulting in coverage from 1995 up to one year prior to the date of data extraction. Data related to diagnosis, procedures, medication use, sociodemographic indications, and hospital stay are all available. Data on dates of pregnancy and births, first names, and family names are used to facilitate the link between mothers and babies by each provincial data custodian. All related obstetric, birth, and offspring outcomes are captured through code bases algorithms. Data related to breastfeeding is not currently captured. Centre Hospitalier Universitaire Sainte-Justine will be the data access provider for CaMCCo for this study.

9.4.2 France: Système National des Données de Santé

The Système National des Données de Santé (SNDS), the French National Health Insurance database, is a national healthcare aggregated database covering approximately 97% of the French population from birth or immigration through death or emigration. Data is available from 2006 up to a one-year lag from date of data extraction with annual refreshes. Leveraging a unique pseudonymised identifier, the SNDS links all reimbursed outpatient claims across healthcare insurance schemes from the Datamart de Consommation Inter-Regimes (DCIR) database with hospital discharge summaries from the Programme de Médicalisation des Systèmes d'Information (PMSI) database, and mortality data from the national death registry. Individual pregnancy episodes are identified through a validated code-based algorithm based

on discharge diagnosis and medical procedures (Blotière, 2018; Goueslard, 2020). Linkages to subsequent births are made through a unique identifier to any birth event (live or non-live) occurring after 22 weeks of gestation. All reimbursed medication exposures are captured across all settings. Drugs are classified with the ATC classification and outpatient medical procedures are coded according to the Classification Commune des Actes Médicaux (CCAM). Evidence of medical history or active comorbidities of a related diagnosis is derived from an ICD-10 based algorithm. Only COVID-19 diagnoses that lead to hospitalisation are currently captured in SNDS through evidence of diagnosis from a hospital discharge; subject-level linking to national databases for COVID-19 vaccination (système d'information Vaccin Covid, VAC-SI) and testing (Système d'Informations de dépistage populationnel, SI-DEP) can be conducted for complete ascertainment of COVID-19 vaccination and diagnosis status. Covariates such as birth year, gender, and area of residence are all available for each mother. Bordeaux PharmacEpi (BPE), affiliated with the University of Bordeaux, will be the data access provider for SNDS for this study.

9.4.3 US: HealthVerity: Maternal Outcomes Masterset

The HealthVerity Maternal Outcomes Masterset (HV MOM) database is a de-identified healthcare aggregated database of over 150 million pregnant women and newborns including, closed medical and pharmacy claims from over 150 payers (commercial and Medicaid), lab, EMR, hospital chargemaster, and mortality data. The dataset is refreshed every 4 months and covers encounters from 1 January 2014 up to 4 months from the date of data extraction. Linkages between the mother and baby are established through a de-identified crosswalk that leverages the mother's age, birth event claims, subscriber and group ID, diagnosis, and procedure codes. All longitudinal treatment data on dispensed prescriptions, inpatient and outpatient diagnosis, treatment, and procedures are ascertained through code-based algorithms combining Healthcare Common Procedure Coding System (HCPCS), ICD, and NDC codes via evidence from administrative claims. Related obstetric, birth, and offspring outcomes are ascertained through code-based algorithms using P- and Z-ICD codes. Subject-level date of death (month and year) is derived from an external source (Private Source 90) that combines over 40,000 sources with a 3-month lag. Key confounders such as age, sex, race/ethnicity, and payer are available for every mother. Mothers and babies are continuously followed-up through the end of the mother's enrolment on an insurance plan.

9.5 Study Size

To estimate the expected number of EVUSHELD-exposed pregnancies we may observe within the proposed countries in this study, we used currently available US data given EVUSHELD's earlier date of approval in the US than other countries. Specifically, based on a preliminary feasibility assessment, 60 women were exposed to EVUSHELD since EUA until 31 March 2022 (representing 4 months of data) in the HV MOM. Within this group, a total of 8 women over 20 years old with 365 days of enrolment, who were pregnant in the prior year,

and had a high-risk condition in the 365 days prior to LMP were exposed to EVUSHELD. The expected number of EVUSHELD-exposed pregnancies by dataset will be updated as more data becomes available during the conduct of the study.

Precision calculations were performed for the descriptive analysis. These calculations are based on the prevalence of outcomes of interest in the unexposed population. Values of 0.01 represent the observed prevalence in outcomes such as stillbirth (110) and ectopic pregnancy (111,112). A prevalence close to 0.05 is relevant for outcomes like major congenital malformations (46,113,114). Outcomes such as preterm birth and small for gestational age have a prevalence of approximately 0.10 (115,116). Finally, spontaneous abortions have an observed prevalence close to 0.15 (117,118). [Table 10](#) presents the 95% CIs using the Wilson score method associated with each background prevalence as a function of sample size (Wilson, 1927). Confidence intervals were computed using R (v4.1.1) with the *binom* package (v4.7-1). For example, a sample size of 100 pregnancies examining preterm birth and assuming a true prevalence of 0.10 would result in a 95% CI estimate for prevalence of 0.055 to 0.174. These CIs would apply regardless of the EVUSHELD exposure status.

Table 10 Precision Around Prevalence Estimates for Descriptive Outcomes

Background prevalence	Sample size				
	50	75	100	150	200
0.01	0.004; 0.105*	0.002; 0.072*	0.002; 0.054	0.004; 0.047*	0.003; 0.036
0.05	0.021; 0.162*	0.021; 0.129*	0.022; 0.112	0.027; 0.102*	0.027; 0.090
0.10	0.043; 0.214	0.055; 0.197*	0.055; 0.174	0.062; 0.158	0.066; 0.149
0.15	0.083; 0.285*	0.094; 0.259*	0.093; 0.233	0.104; 0.220*	0.107; 0.206

*For calculation purposes, the number of events (successes of the binomial distribution) was rounded up to an integer (minimum 1). For example, when the background prevalence is 0.01 and the sample size is 50, the number of events was set to one. If the prevalence was 0.05 and the sample size was 75, the number of events was set to 4.

Considering potential rare exposure and low background prevalence of some outcomes, the cumulative binomial probability of observing at least one and 5 events is presented as a function of sample size in [Table 11](#). These probabilities were computed using the *dbinom* function of the default *stats* package in R (v4.1.1).

For example, a sample size of 100 pregnancies examining preterm birth and assuming a true prevalence of 0.10 would result in a probability of >0.999 for observing at least 1 event.

Table 11 Cumulative Binomial Probability of Observing at Least 1 Event, and at Least 5 Events for Descriptive Outcomes

Background prevalence	Number of events and sample size									
	1					5				
	50	75	100	150	200	50	75	100	150	200
0.01	0.395	0.529	0.634	0.779	0.866	<0.001	0.001	0.003	0.018	0.052
0.05	0.923	0.979	0.994	>0.999	>0.999	0.104	0.321	0.564	0.874	0.974
0.10	0.995	>0.999	>0.999	>0.999	>0.999	0.569	0.881	0.976	0.999	>0.999
0.15	>0.999	>0.999	>0.999	>0.999	>0.999	0.888	0.992	>0.999	>0.999	>0.999

9.6 Data Management

Across the proposed data sources, Aetion will have oversight of the data management activities for the HV MOM dataset. Each of the selected research partners will have oversight of data management activities for SNDS and CaMCCO and will follow their respective standard operating procedures.

HV MOM will be loaded into the Aetion Evidence Platform (AEP) after minimal processing of individuals' longitudinal timelines to enable representation of the original data without any data loss. Data checks will be implemented to ensure:

- Events have a valid start date.
- Record counts are cross-checked for validation and compared to the original data counts.
- Enrolment information, if available, is processed and checked; all fields and sample records are checked to ensure validity.

Data quality checks typically include, but are not limited to, programming checks by an individual who is not a main programmer for the study, internal dataset consistency, and include checks to ensure that protocol criteria are met. If the outcomes of the validation checks are not satisfactory, then an examination of the problem is performed on the dataset(s) until the issues are resolved. All data validation, quality checks, and resolution of issues identified and resolved will be appropriately documented.

Preliminary SNDS data quality checks are performed and programmed within the SAS Enterprise Guide platform and typically include:

- Received files are transferred to BPE internal server with a hash process before/after transfer to check their integrity and are compared with a list of expected files to identify any potential missing or incomplete information.
- Ensuring the absence of “sensitive” identifying variables.

- Counts of subjects are compared with expected counts.
- Record rows of each file are checked, before and after the cleaning process (according to the French National Health Insurance Fund (CNAM) recommendations).
- Figures with monthly numbers of healthcare are edited to identify and prevent any data loading problem.
- Files are cross-checked to verify the consistency of linkages between them.

Reports are automatically edited, and programme logs are saved on BPE server. All documents are reviewed and validated by appropriately qualified data managers/statisticians. In case of issues (missing data, files, etc.), the CNAM is informed and returns updated files within an agreed timeframe. In cases of inconsistency identified within the dataset outputs, programs may be edited and adapted; processes are re-run until the problem(s) is solved.

For other data sources, the data management process will include the following checks which are performed at data acquisition, to ensure compliance and completeness:

- File completeness check
- File formatting versus the predefined standard(s)
- Data content – whether all fields are present with corresponding values

Data-processing checks include:

- Control for correctness of the format and any input file format transformations
- Control of correctness of the bridged data

Processed-data checks include:

- Control of individual data-suppliers - total data volume versus expected and previous periods
- Checks for missing data estimations
- Check for aggregated data by analysis unit, eg, values for surgeries, hospitals, regions

A series of descriptive statistics are run to validate the integrity of the field content. These statistics include but are not limited to:

- Record counts within each data table
- Unique counts of patients
- Unique counts of patients continuously enrolled for specified one-year increments
- Percentage of missing values in key data fields (eg, date of birth, gender, billing and diagnosis codes, dates of service, etc.)
- Percentage of valid values in key data fields

- Verify that a unique patient identifier is linked to only one individual

9.7 Data Analysis

Data from countries other than the US will be analysed separately by research partners using R version 3.5.0 (or higher) or SAS Enterprise Guide on the basis of this protocol. In the US, analysis of the HV MOM dataset will be conducted on the AEP or using R version 3.5.0 (or higher) by Action team members. Database-specific results of each descriptive and exploratory comparative analysis will be pooled using meta-analysis.

All analyses described below (including the sensitivity analyses and meta-analysis) will be further detailed in the final SAP. The SAP may update the data analysis specifications detailed in this protocol. Significant updates made to the definition of the primary outcomes before the execution of analyses, if any, will be addressed by a protocol and/or SAP amendment.

9.7.1 Creation of Analytic Cohorts Via Coarsened Exact Matching

To ensure that, within each outcome-specific analysis, outcome risk is characterised in comparable groups of exposed and unexposed pregnancies, each eligible EVUSHELD exposed pregnancy will be matched to all possible unexposed pregnancies using coarsened exact matching (CEM) (CEM matched set) for contextualisation purposes. Since definitions of etiologically relevant exposure windows and outcomes assessment periods are outcome-specific, CEM will be performed to derive 5 distinct groups of analytic cohorts:

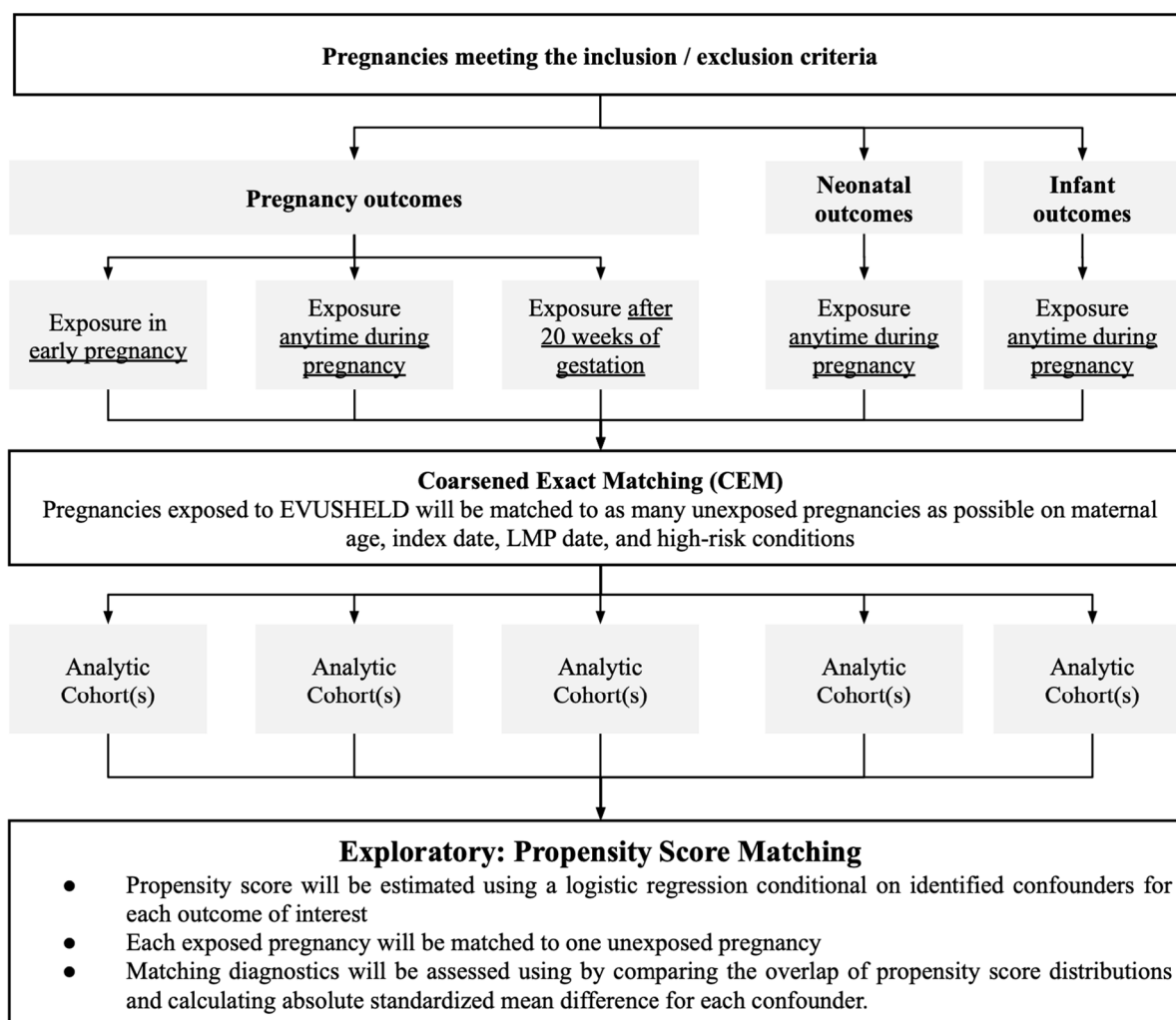
- Pregnancy outcomes:
 - Pregnancy outcomes potentially associated with exposure in early pregnancy and measured prior to 20 weeks gestation
 - Pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured anytime during pregnancy
 - Pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured after 20 weeks gestation
- Offspring outcomes:
 - Neonatal outcomes measured in the first 28 days of life
 - Infant outcomes measured in the first year of life

See Section 9.1 for a summary of the outcome-specific study design and Section 9.3.2 for operational definitions of study outcomes.

For each analytic cohort, exposed pregnancies will be matched to as many unexposed pregnancies as available based on maternal age (with at most ± 2 years window), index date (with at most ± 14 days window), LMP date (with at most ± 14 days window), and high-risk

condition group (severely immunocompromised, conditions with severe risk of COVID-19 disease progression, and conditions with moderate risk of COVID-19 disease progression) to control for the potential confounding effects of maternal age, gestational age, and seasonality. To ensure comparability between groups, clinical activity among unexposed pregnancies will be required (with at most ± 14 days window) at the time of EVUSHELD injection in its matched EVUSHELD exposed pregnancy. Each pregnancy can only be classified as exposed or unexposed within one analytic cohort. However, a pregnancy may be included in multiple analytic cohorts (as either exposed or unexposed) based on cohort-specific inclusion requirements. For example, if a first dose of EVUSHELD is administered at the end of pregnancy, this pregnancy will be considered as unexposed for the spontaneous abortion analytic cohort (since pregnancies can only be exposed to EVUSHELD during the first 19 weeks of pregnancy for this outcome) and will be considered as exposed for analytic cohorts with an exposure ascertainment period spanning from LMP date to end of pregnancy. The complete matching process is depicted in [Figure 6](#). Matching on propensity score will be explored for comparative analyses and is described in further detail in [Section 9.7.4.1](#).

Figure 6 Overview of the Matching Procedures



9.7.2 Primary Analyses

9.7.2.1 Descriptive Analysis of Baseline Characteristics

For each analytic cohort, a descriptive analysis of baseline characteristics will be conducted stratified by EVUSHELD exposure. Baseline characteristics (including demographics, pregnancy characteristics and history, laboratory tests, comorbidities, co-medications and substance abuse, COVID-19 vaccine and disease status; offspring sex, breastfed, and infections) will be evaluated over the confounder ascertainment period (baseline period) or as noted in Section 9.3.3.

For categorical variables, frequency (number of cases, N) and percentage (%) of observations in each exposure group will be reported. For continuous variables, results will be presented as the mean with standard deviation (SD), the median, and interquartile range (IQR). The proportion of missing values per confounder will be reported.

9.7.2.2 Descriptive Analysis of Pregnancy and Offspring Outcomes

Descriptive analyses of pregnancy and offspring outcomes will be conducted in the respective CEM-matched (for main analysis) and propensity score (PS)-matched (for exploratory analysis) cohorts. The list of outcomes to be described is included in Section 9.3.2.

Following guidance on methods for the evaluation of medicines in pregnancy and breastfeeding by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) (119), the risk with associated 95% confidence interval of each outcome will be reported in pregnancies with EVUSHELD exposure and pregnancies without EVUSHELD exposure. Confidence intervals will be computed using the Wald method (normal approximation) if $np(1-p) \geq 5$ (with n representing the number of patients and p the observed proportion of events). If $np(1-p) < 5$, the exact method or Wilson score will be used.

9.7.3 Secondary Analyses

9.7.3.1 Descriptive Analysis of Exposure Characteristics

The EVUSHELD exposure characteristics (described in Section 9.3.1) of EVUSHELD-exposed pregnancies will be summarised descriptively. For categorical variables, frequency (number of cases, N) and percentage (%) of observations will be reported. For continuous variables, results will be presented as the mean with SD, the median, and IQR. The proportion of missing values per characteristic will be presented.

9.7.3.2 Descriptive Analysis of Outcomes by Subgroups

Pregnancy and offspring outcomes will be described among EVUSHELD-exposed pregnancies within strata of individual and pregnancy characteristics including:

- Maternal age
- High-risk condition type
- Trimester of index date
- Recent SARS-COV-2 infection
- Timing of last SARS-COV-2 vaccination relative to gestation
- Other SARS-COV-2 monoclonal antibody users

Risks with associated 95% confidence interval of each outcome will be reported in each stratum stratified by EVUSHELD exposure status. See Section 9.7.2.2 for the calculation method of the confidence intervals.

9.7.4 Comparative Exploratory Analyses

Comparative exploratory analyses of pregnancy and offspring outcomes will be conducted in the respective analytic cohorts, with the results presented in the final report. The list of outcomes is included in Section 9.3.2.

These exploratory analyses will be conducted if sufficient sample size is achieved at the time of the final analysis only.

9.7.4.1 Propensity Score Matching

In each analytic cohort, confounding control will be further addressed by implementing PS matching (120). The propensity score is defined as the probability of EVUSHELD exposure conditional on baseline covariates and will be estimated via multivariable logistic regression. The list of potential confounders selected for each outcome of interest can be found in [Table 8](#) and [Table 9](#). Each exposed pregnancy will be matched to one unexposed pregnancy using nearest-neighbour PS matching within their CEM set (Section 9.7.1). Diagnostic tools (such as PS overlap among EVUSHELD exposed and unexposed patients) will inform PS matching options such as the use of a calliper and its width. Covariate balance will be assessed by comparing absolute standardised mean difference (ASD) pre- and post-PS matching for each covariate. If more than 90% of the covariates have an $ASD < 0.10$, exposure groups will be considered balanced. If balance is not achieved in 10% or more of the covariates, unbalanced confounders will be included in the outcome model as covariates.

In case propensity score matching leads to severe depletion of the analytic cohort (at least 10%), alternative confounding control methods (eg, propensity score weighting or covariate balancing propensity score) will be evaluated.

9.7.4.2 Estimation of Risk Ratios and Risk Differences

Risk ratios will be estimated by robust (modified) Poisson regression using a log link and a Poisson distribution without an offset parameter (121). Robust variance estimation will be used to avoid overestimating standard errors of estimates. Poisson regression models are widely used to estimate risk ratios for both common and rare outcomes (122). The robust Poisson regression (ie, Poisson regression with robust standard errors) allows to consider clustering (eg, the same individual can contribute with multiple pregnancies to the analytic cohort) and has been shown to perform better than the log-binomial Poisson regression for clustered prospective data (123) and under model misspecification (124).

Risk differences will be estimated by Poisson regression using an identity link with robust standard errors (125).

Estimates will be reported alongside their 95% confidence intervals. Statistical significance for all comparative analyses is set at a test size (alpha) of 0.05.

Pregnancy and offspring will be the statistical units of analysis. Appropriate statistical tools will be implemented to address the fact that the same individual can contribute with multiple pregnancies to the analytic cohort (ie, robust standard errors). A detailed description of the modelling techniques (including informative censoring adjustments) will be described in the SAP.

Some analyses may be deemed unfeasible if sample sizes are too small (less than 20 observations).

9.7.5 Meta-analyses

As described in Section 9.7, data from countries other than the US will be analysed by research partners and it will not be possible to pool pregnancy-level data across locations.

For the primary analysis, a pooled risk estimate with 95% confidence interval will be estimated for each outcome using a meta-analysis of risk from the database-specific risk results. The inverse variance method assuming a binomial distribution of risk estimates will be used. The double arcsine transformation will be considered to stabilise the variance and avoid the possible estimation of a lower confidence interval limit below zero in instances of rare outcomes (126).

For the exploratory comparative analyses, a meta-analysis of each database-specific estimate (for each outcome of interest) will be implemented using aggregate data. Risk ratios will be log transformed prior to pooling, and pooled risks ratio and 95% confidence interval will be computed to summarise effect estimates. For risk differences, a varying coefficient model will be applied (127).

For both meta-analyses, since differences in dosing and/or target populations across countries are expected based on current EVUSHELD recommendations, a random-effect model will be considered to allow for the possibility that the underlying true effect may not be the same for all database-specific analysis. This model will consider hidden or unmeasured sources of variability by incorporating such variability when computing the weighted average summary estimate, producing wider confidence intervals compared to the fixed-effect model (128). If no substantial differences in dosing (eg, each dose administered is 600 mg) and target population for EVUSHELD (ie, similar high-risk conditions profile across countries) are observed, then a fixed-effect model, without adjustment to the estimated standard error for sample overlap, may be considered. In this type of approach, the pooled effect estimate is a weighted average of the database-specific estimates, using the inverse variance of the estimates as the weight.

The I^2 statistic will be used to quantify the study results variability (129). It estimates the proportion of variability in point estimates due to heterogeneity rather than sampling error.

9.7.6 Missing Data

Missing data will be reported as counts and proportions in descriptive analyses for each relevant covariate (variables for which a value would be expected for all pregnancies, such as age or sex). In case of substantial missing data (eg, greater than 10% per covariate), multiple

imputation techniques such as fully conditional specification, will be considered for the comparative analyses.

9.7.7 Sensitivity Analysis

9.7.7.1 Bias Analysis for Potential Unmeasured Confounding

The E-value will be calculated to assess the impact of unmeasured confounders (130). The E-value is the minimum strength of association, on the risk ratio scale, that an unmeasured confounder would need to have with both the treatment and the outcome to fully explain away a specific treatment-outcome association, conditional on the measured covariates. The E-value will be computed for all estimators of interest. Further details will be provided in the SAP.

9.7.7.2 Alternative PS Modelling

Alternative PS modelling techniques such as high dimensional propensity score (hdPS) (131) or Targeted Maximum Likelihood Estimation (132) will be implemented to assess the robustness of inferences to PS model specification.

9.7.7.3 Alternative Outcome Modelling

For all outcomes in the exploratory comparative analyses, except for maternal death, odds ratios via logistic regression will be estimated to assess the robustness of inferences from the main estimators to alternative model specifications. Robust standard errors will be estimated to address clustering induced by allowing the same individual to contribute with more than one pregnancy to the analytic cohort. For maternal death, as sensitivity analysis, a Poisson regression model with an offset will be implemented to estimate maternal mortality rate.

9.7.7.4 Dose Response Analysis

Ordinal multinomial exposure indicators will be used to assess the impact of dosage on the risk between the exposure and the outcomes of interest for the exploratory comparative analyses. In particular, 2 multinomial exposure indicators will be considered: (1) Number of EVUSHELD injections (0, 1, 2, 3 or more) and (2) cumulative dose of EVUSHELD (0 mg, 300, 600, 900 mg or more) (133).

9.7.7.5 Country-specific Analysis

Where country variation exists for an outcome definition, country-specific definitions will be detailed in the SAP and sensitivity analyses for the primary objectives will be run.

9.8 Quality Control

For the HV MOM dataset, before the databases are connected to the AEP, raw data review is conducted to understand contents of the data table(s), establish relationships, and help inform the connector specification process. Scientific integrity checks are also performed as a part of this step to understand if the contents of the data shipment are consistent with the expected

data as laid out in the applicable data usage agreement. Some of the key characteristics explored in this process include:

- Table structure (number of rows, columns, column names etc.)
- Summary counts per table (ie, non-missing counts, unique counts)
- Variable distribution (eg, min, mean, median, max for numeric variables; top frequencies for categorical variables)
- Date range (min, max and distribution over a time period)
- Missingness percentage of attributes

Aetion performs a 2-step process to validate all database connections: Data Engineers build the connector based on a validated specification document as developed by Aetion data scientists. In parallel, an Aetion Data Science/Integration team develops validation code that serves as a quality check (eg, event, patient etc. counts match up with the raw data). The AEP enables the preservation of the robustness of the raw data while ensuring regulatory-grade quality analysis.

During the statistical analysis, all steps and decisions made are documented within the AEP using automatic audit logs that cannot be deleted. All variables, cohorts and analysis will be reviewed throughout the implementation process by multiple scientists to ensure validity.

For other datasets handled by research partners (SNDS and CaMCCo), a description (counts, distribution, percentages, etc.) of key characteristics (such as socio-demographic variables, specific diagnosis or medication codes, date range, etc.) is performed to identify missing or erroneous information. Review processes are implemented to guarantee high standards regarding programming. An independent double programming/code review will be performed for main criteria and analysis, and the results compared for validation. All statistical logs are kept and can be provided. All statistical results are reviewed throughout the analysis process and discussed by project team members including the senior statistician.

A summary of quality control procedures followed by each research partner will be stored in the study file.

9.9 Limitations of the Research Methods

9.9.1 Limitations Addressed in Design and Analyses

The following limitations have been addressed via the design of the study and analyses, but will also be taken into consideration when interpreting the findings:

- **Misclassification of LMP / gestational age:** Validated algorithms for identifying the date of pregnancy start will be used. However, even minor errors in classifying gestational age may have important implications for exposure and outcome ascertainment.

For instance, a spontaneous abortion may be misclassified as a stillbirth if gestational age is overestimated by even one week. Such misclassification is anticipated to be unrelated to pregnancy exposure status.

- **Immortal time bias:** Immortal time bias increases the likelihood that shorter pregnancies will be classified as unexposed when the outcome is dichotomous. This is particularly relevant for outcomes dependent on longer gestations (ie, live birth or stillbirth) and the risk of adverse outcomes such as major congenital malformations are likely to be underestimated (134).
- **Differential Left Truncation:** Left-truncation refers to the situation in which data preceding the outcome of interest are not available at the time of the measurement (135). This is notably applicable for spontaneous abortions. Left truncation also plays a role when early pregnancy outcomes are not captured as the pregnancy may have been undetected at the time of the outcome. Left truncation can result in inadequate exposure assessment and in the incomplete capture of study endpoints. Bias is introduced when the contribution of time-at-risk varies between the exposed and unexposed due to non-observability in the data.
- **Clustering resulting in violations of the independence assumption:** Inclusion of multiple pregnancy episodes per individual creates the potential for within-family correlation, thereby violating the independence assumption (119). Appropriate statistical tools (eg, calculation of robust standard errors) will be implemented to address the fact that the same individual can contribute to the analytic cohort with multiple pregnancies.
- **Confounding by indication:** Allocation of EVUSHELD is likely due to higher risk of poor prognosis if infected with SARS-CoV-2 based on a patient's pre-existing condition. The likelihood that individuals receive EVUSHELD varies across study participants. Factors such as physician's prognosis, concomitant medications, and history of other diseases can influence the probability of drug administration (136). Despite matching on high-risk condition group, the underlying risk profile is likely to vary between EVUSHELD-exposed and unexposed pregnancies. It is likely that residual confounding by indication will remain after matching. Hence, the distribution of high-risk conditions and high-risk groups among EVUSHELD-exposed and unexposed pregnancies will be provided in the progress reports for contextualisation purposes. Results from the exploratory comparative analyses should be interpreted with caution.
- **Misclassification of covariates and residual confounding** (applicable for exploratory comparative analyses): Measured covariates of interest may be subject to misclassification. For instance, COVID-19 vaccination and infection status is known to be underreported in claims and EMR data sources (137,138). SARS-CoV-2 variants will be likely unavailable in data sources considered. Most studies on SARS-CoV-2 infections have been conducted before the current study time period and the testing paradigm has shifted. All mild and asymptomatic cases are likely to be misclassified in any data source considered. It is likely that SARS-CoV-2 infection definition will mostly capture severe forms. Even though SARS-CoV-2 infections will be assessed across the confounder ascertainment period (ie, baseline period), they are likely to be underestimated considering self-testing. Nonetheless, this is unlikely to be differential across treatment status. Potential confounders such as family history of pregnancy complications and poor

birth outcomes, pregnancy and birth history and substance abuse may not be adequately captured within secondary claims / EHR data sources.

- Further, while underlying conditions that may lead to use of EVUSHELD prior to or during pregnancy will be measured, severity of those conditions (a potential risk factor for adverse pregnancy and birth outcomes) are not captured. In addition, socio-economic status, behavioural risk factors, COVID-19 exposure risk, and race / ethnicity data are not captured within all databases. Thus, residual confounding may impact effect estimates despite use of PS methods to minimise differences between EVUSHELD-exposed and unexposed pregnancies. hdPS or Targeted Maximum Likelihood Estimation methods will be used in addition to propensity score matching (or weighting, in the event matching results in substantial depletion of the analytic cohort) to further minimise the possibility of residual confounding. Quantitative bias analysis techniques (Section 9.7.7.1) will be applied to evaluate the extent of potential unmeasured confounding.

9.9.2 Limitations to be Considered in Interpretation Only

The following limitations will be taken into consideration when interpreting the findings from the implementation of this protocol:

- **Misclassification of spontaneous abortion:** Spontaneous abortions occurring without a corresponding medical encounter (more likely for spontaneous abortions occurring early in pregnancy) will not be captured, and thus the risk will be underestimated for both EVUSHELD-exposed and unexposed pregnancies. This misclassification may result in bias if spontaneous abortions occurring in EVUSHELD-exposed pregnancies tend to occur earlier than those in unexposed pregnancies. Nonetheless, this is unlikely to be differential across treatment status since all women included will be eligible for EVUSHELD.
- **Comparison of the magnitude of effect estimates across outcomes:** Each outcome implies a different cohort and PS model and therefore the magnitude of effect estimates across outcomes cannot be compared.
- **Exclusion of pregnancies with in vitro fertilisation or other assisted reproductive technology:** Women using immunosuppressive medications may have reduced fertility leading to the use of in vitro fertilisation or other assisted reproductive technology. The exclusion of pregnancies using these techniques may introduce selection bias. Results may not be generalised to all women of reproductive age using immunosuppressive medications. The number of pregnancies excluded with this criterion will be considered when interpreting the study results.
- **Database-specific algorithms:** exposure, outcomes and covariates operational definitions may be adapted in each country based on database-specific algorithms or local coding systems (33,34,139,140). This will be further specified in the SAP. Database-specific nuances and limitations will be detailed in the study report.

9.10 Other Aspects

Not applicable.

10 PROTECTION OF HUMAN SUBJECTS

All data used for the proposed study will comply with local regulations and will be performed in accordance with the Declaration of Helsinki, International Council for Harmonisation Good Clinical Practices (ICH GCPs), Green Public Procurement (GPP), and the applicable legislation on Non-Interventional Studies and/or Observational Studies. This is a secondary analysis of de-identified and/or anonymised data without access to personal identifying information and without direct enrolment of patients (eg, in contrast to interventional studies or other primary data collection studies requiring patient participation). All patient-level and provider-level data within the database contain synthetic identifiers to protect the privacy of individuals and data contributors. All study reports will contain aggregated data only that cannot be used to identify individual patients or physicians. Thus, informed consent is not applicable.

AstraZeneca will not have access to the patient-level data at any time of the study.

The HealthVerity MOM dataset is a de-identified, Health Insurance Portability and Accountability Act (HIPAA)-certified dataset. Date shifting and masking of identifiable variables is done to remove the risk of patient re-identification and retain HIPAA certification. For these reasons, Aetion believes that this study qualifies for an exemption by the Wirb Copernicus Group Institutional Review Board (WCG-IRB). Exemption determination and HIPAA full waiver of authorisation will be sought for use of this dataset and the IRB letter will be stored in the study file.

In addition, for the other datasets, each research partner will obtain appropriate reviews or exemption determinations from local ethics committees.

11 MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study involves data that exist as structured data by the time of study start or will be supplemented with data obtained from natural language processing from unstructured data during study execution (ie, secondary data reuse). In these data sources, individual patient data are not retrieved or validated, and it is not possible to link (ie, identify a potential association between) a particular product and medical event to an identifiable individual. Thus, the minimum criteria for reporting an adverse event (AE) (ie, identifiable patient, identifiable reporter, a suspect product, and event) cannot be met. Accordingly, AEs are not reportable within this study.

12 PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

The study will be registered in the EU PAS register upon finalisation. Progress reports, including relevant information to document the status of the study, will include information regarding current pregnant patient counts with key baseline characteristics, product uptake, distribution of high-risk conditions and high-risk groups among EVUSHELD-exposed and unexposed pregnancies, and deviations from the original study design or considerations on the study design. Yearly interim analyses will encompass the primary and secondary analyses in the groups of exposed and unexposed pregnancies (refer to Section 9.7.2 and Section 9.7.3). Additionally, all adverse events/reactions collected for the current study will be recorded and summarised in the interim safety analysis and in the final study report per Good Pharmacovigilance Practices (GVP) module VI. Following study completion and finalisation of the study report, the abstract and/or full results of this observational, non-interventional study will be posted in the EU PAS register. All publications will comply with the International Committee of Medical Journal Editors (ICMJE) guidelines.

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139.Quantin C. ETUDE DES ALGORITHMES DE DEFINITION DE PATHOLOGIES
DANS LE SYSTEME NATIONAL D'INFORMATION INTER-REGIMES DE
L'ASSURANCE MALADIE (SNIIRAM) Première Partie. :272.

140.Quantin C. ETUDE DES ALGORITHMES DE DEFINITION DES PATHOLOGIES
DANS LE SYSTEME NATIONAL D'INFORMATION INTER-REGIMES DE
L'ASSURANCE MALADIE (SNIIRAM) Deuxième Partie. :56.

Appendix A List of Stand-alone Documents

Table 12 List of Stand-Alone Documents

Number	Document reference number	Date	Title
1	Annex 1	19 September 2022	Code list
2	Annex 2	19 September 2022	Feasibility report
3	Annex 3	19 September 2022	EVUSHELD dosing recommendations

Appendix B ENCePP Checklist for Study Protocols

Study title: *A non-interventional multi-country cohort study to assess the safety of EVUSHELD™ (Tixagevimab/Cilgavimab) during pregnancy*

EU PAS Register® number: Not registered
Study reference number (if applicable): N/A

<u>Section 1: Milestones</u>	Yes	No	N/A	Section Number
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection ¹	☒	☐	☐	6
1.1.2 End of data collection ²	☒	☐	☐	6
1.1.3 Progress report(s)	☒	☐	☐	6
1.1.4 Interim report(s)	☒	☐	☐	6
1.1.5 Registration in the EU PAS Register®	☒	☐	☐	6
1.1.6 Final report of study results.	☒	☐	☐	6

Comments:

<u>Section 2: Research question</u>	Yes	No	N/A	Section Number
2.1 Does the formulation of the research question and objectives clearly explain:	☒	☐	☐	8.1-8.4
2.1.1 Why the study is conducted? (eg to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue)	☒	☐	☐	7
2.1.2 The objective(s) of the study?	☒	☐	☐	8.1-8.4
2.1.3 The target population? (ie population or subgroup to whom the study results are intended to be generalised)	☒	☐	☐	9.2.1
2.1.4 Which hypothesis(-es) is (are) to be tested?	☐	☐	☒	

¹ Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.

² Date from which the analytical dataset is completely available.

<u>Section 2: Research question</u>	Yes	No	N/A	Section Number
2.1.5 If applicable, that there is no <i>a priori</i> hypothesis?	☐	☐	☒	

Comments:

The study is descriptive in nature, with exploratory comparative objectives and no hypothesis is to be tested.

<u>Section 3: Study design</u>	Yes	No	N/A	Section Number
3.1 Is the study design described? (eg cohort, case-control, cross-sectional, other design)	☒	☐	☐	9.1
3.2 Does the protocol specify whether the study is based on primary, secondary or combined data collection?	☒	☐	☐	9.4
3.3 Does the protocol specify measures of occurrence? (eg, rate, risk, prevalence)	☒	☐	☐	9.7.2.1
3.4 Does the protocol specify measure(s) of association? (eg risk, odds ratio, excess risk, rate ratio, hazard ratio, risk/rate difference, number needed to harm (NNH))	☒	☐	☐	9.7.4.2
3.5 Does the protocol describe the approach for the collection and reporting of adverse events/adverse reactions? (eg adverse events that will not be collected in case of primary data collection)	☒	☐	☐	12

Comments:

<u>Section 4: Source and study populations</u>	Yes	No	N/A	Section Number
4.1 Is the source population described?	☒	☐	☐	9.2.1
4.2 Is the planned study population defined in terms of:				
4.2.1 Study time period	☒	☐	☐	9.1.2
4.2.2 Age and sex	☒	☐	☐	9.2.1
4.2.3 Country of origin	☒	☐	☐	9.1.1
4.2.4 Disease/indication	☒	☐	☐	7
4.2.5 Duration of follow-up	☒	☐	☐	9.2.1
4.3 Does the protocol define how the study population will be sampled from the source population? (eg event or inclusion/exclusion criteria)	☒	☐	☐	9.2.2/3

Comments:

<u>Section 5: Exposure definition and measurement</u>	Yes	No	N/A	Section Number
5.1 Does the protocol describe how the study exposure is defined and measured? (eg operational details for defining and categorising exposure, measurement of dose and duration of drug exposure)	☒	☐	☐	9.3.1
5.2 Does the protocol address the validity of the exposure measurement? (eg precision, accuracy, use of validation sub-study)	☒	☐	☐	9.5
5.3 Is exposure categorised according to time windows?	☒	☐	☐	9.3.1
5.4 Is intensity of exposure addressed? (eg dose, duration)	☒	☐	☐	9.3.1
5.5 Is exposure categorised based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☒	☐	☐	9.3.1
5.6 Is (are) (an) appropriate comparator(s) identified?	☒	☐	☐	9.3.3

Comments:

Section 9.3.3 identifies other SARS-CoV-2 monoclonal antibodies

<u>Section 6: Outcome definition and measurement</u>	Yes	No	N/A	Section Number
6.1 Does the protocol specify the primary and secondary (if applicable) outcome(s) to be investigated?	☒	☐	☐	9.3.2
6.2 Does the protocol describe how the outcomes are defined and measured?	☒	☐	☐	9.3.2
6.3 Does the protocol address the validity of outcome measurement? (eg precision, accuracy, sensitivity, specificity, positive predictive value, use of validation sub-study)	☒	☐	☐	9.3.2
6.4 Does the protocol describe specific outcomes relevant for Health Technology Assessment? (eg HRQoL, QALYs, DALYs, health care services utilisation, burden of disease or treatment, compliance, disease management)	☐	☐	☒	

Comments:

Outcomes specific to HTA are not included in the list of studied outcomes.

<u>Section 7: Bias</u>	Yes	No	N/A	Section Number
7.1 Does the protocol address ways to measure confounding? (eg confounding by indication)	☒	☐	☐	9.7.7.1
7.2 Does the protocol address selection bias? (eg healthy user/adherer bias)	☒	☐	☐	9.9.1
7.3 Does the protocol address information bias? (eg misclassification of exposure and outcomes, time-related bias)	☒	☐	☐	9.9.1

Comments:

<u>Section 8: Effect measure modification</u>	Yes	No	N/A	Section Number
8.1 Does the protocol address effect modifiers? (eg collection of data on known effect modifiers, sub-group analyses, anticipated direction of effect)	☒	☐	☐	9.2.4

Comments:

<u>Section 9: Data sources</u>	Yes	No	N/A	Section Number
9.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
9.1.1 Exposure? (eg pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview)	☒	☐	☐	9.3.1
9.1.2 Outcomes? (eg clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics)	☒	☐	☐	9.3.2
9.1.3 Covariates and other characteristics?	☒	☐	☐	9.3.3
9.2 Does the protocol describe the information available from the data source(s) on:				
9.2.1 Exposure? (eg date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☒	☐	☐	9.4
9.2.2 Outcomes? (eg date of occurrence, multiple event, severity measures related to event)	☒	☐	☐	9.4
9.2.3 Covariates and other characteristics? (eg age, sex, clinical and drug use history, co-morbidity, co-medications, lifestyle)	☒	☐	☐	9.4
9.3 Is a coding system described for:				

<u>Section 9: Data sources</u>	Yes	No	N/A	Section Number
9.3.1 Exposure? (eg WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC) Classification System)	☒	☐	☐	9.3.1
9.3.2 Outcomes? (eg International Classification of Diseases (ICD), Medical Dictionary for Regulatory Activities (MedDRA))	☒	☐	☐	9.3.2
9.3.3 Covariates and other characteristics?	☒	☐	☐	9.3.3
9.4 Is a linkage method between data sources described? (eg based on a unique identifier or other)	☒	☐	☐	9.4.3

Comments:

<u>Section 10: Analysis plan</u>	Yes	No	N/A	Section Number
10.1 Are the statistical methods and the reason for their choice described?	☒	☐	☐	9.7
10.2 Is study size and/or statistical precision estimated?	☒	☐	☐	9.5
10.3 Are descriptive analyses included?	☒	☐	☐	9.7.2
10.4 Are stratified analyses included?	☒	☐	☐	9.7.2.1
10.5 Does the plan describe methods for analytic control of confounding?	☒	☐	☐	9.7.4.1
10.6 Does the plan describe methods for analytic control of outcome misclassification?	☒	☐	☐	9.7.4
10.7 Does the plan describe methods for handling missing data?	☒	☐	☐	9.7.6
10.8 Are relevant sensitivity analyses described?	☒	☐	☐	9.7.7

Comments:

<u>Section 11: Data management and quality control</u>	Yes	No	N/A	Section Number
11.1 Does the protocol provide information on data storage? (eg software and IT environment, database maintenance and anti-fraud protection, archiving)	☒	☐	☐	9.8
11.2 Are methods of quality assurance described?	☒	☐	☐	9.8
11.3 Is there a system in place for independent review of study results?	☒	☐	☐	12

Comments:

<u>Section 12: Limitations</u>	Yes	No	N/A	Section Number
12.1 Does the protocol discuss the impact on the study results of:				
12.1.1 Selection bias?	☒	☐	☐	9.9
12.1.2 Information bias?	☒	☐	☐	9.9
12.1.3 Residual/unmeasured confounding? (eg anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods).	☒	☐	☐	9.9
12.2 Does the protocol discuss study feasibility? (eg study size, anticipated exposure uptake, duration of follow-up in a cohort study, patient recruitment, precision of the estimates)	☒	☐	☐	9.5

Comments:

<u>Section 13: Ethical/data protection issues</u>	Yes	No	N/A	Section Number
13.1 Have requirements of Ethics Committee/ Institutional Review Board been described?	☒	☐	☐	10
13.2 Has any outcome of an ethical review procedure been addressed?	☒	☐	☐	10
13.3 Have data protection requirements been described?	☒	☐	☐	10

Comments:

<u>Section 14: Amendments and deviations</u>	Yes	No	N/A	Section Number
14.1 Does the protocol include a section to document amendments and deviations?	☒	☐	☐	5

Comments:

<u>Section 15: Plans for communication of study results</u>	Yes	No	N/A	Section Number
15.1 Are plans described for communicating study results (eg to regulatory authorities)?	☒	☐	☐	12

<u>Section 15: Plans for communication of study results</u>	Yes	No	N/A	Section Number
15.2 Are plans described for disseminating study results externally, including publication?	☒	☐	☐	12

Comments:

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Name of the main author of the
protocol:

Date: 19/09/2022

Signature: _____

Appendix C Additional Information

Supplemental figures summarising analytic cohort-specific study design and Table 13 defining pregnancy trimesters by country are presented below.

Analytic cohort-specific study design figures for pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured anytime during pregnancy (Figure 7), pregnancy outcomes potentially associated with exposure anytime during pregnancy and measured after 20 weeks gestation (Figure 8), and offspring outcomes (Figure 9) are presented below.

Figure 7 Analytic Cohort Design for Pregnancy Outcomes Potentially Associated with Exposure Anytime During Pregnancy and Measured Anytime During Pregnancy

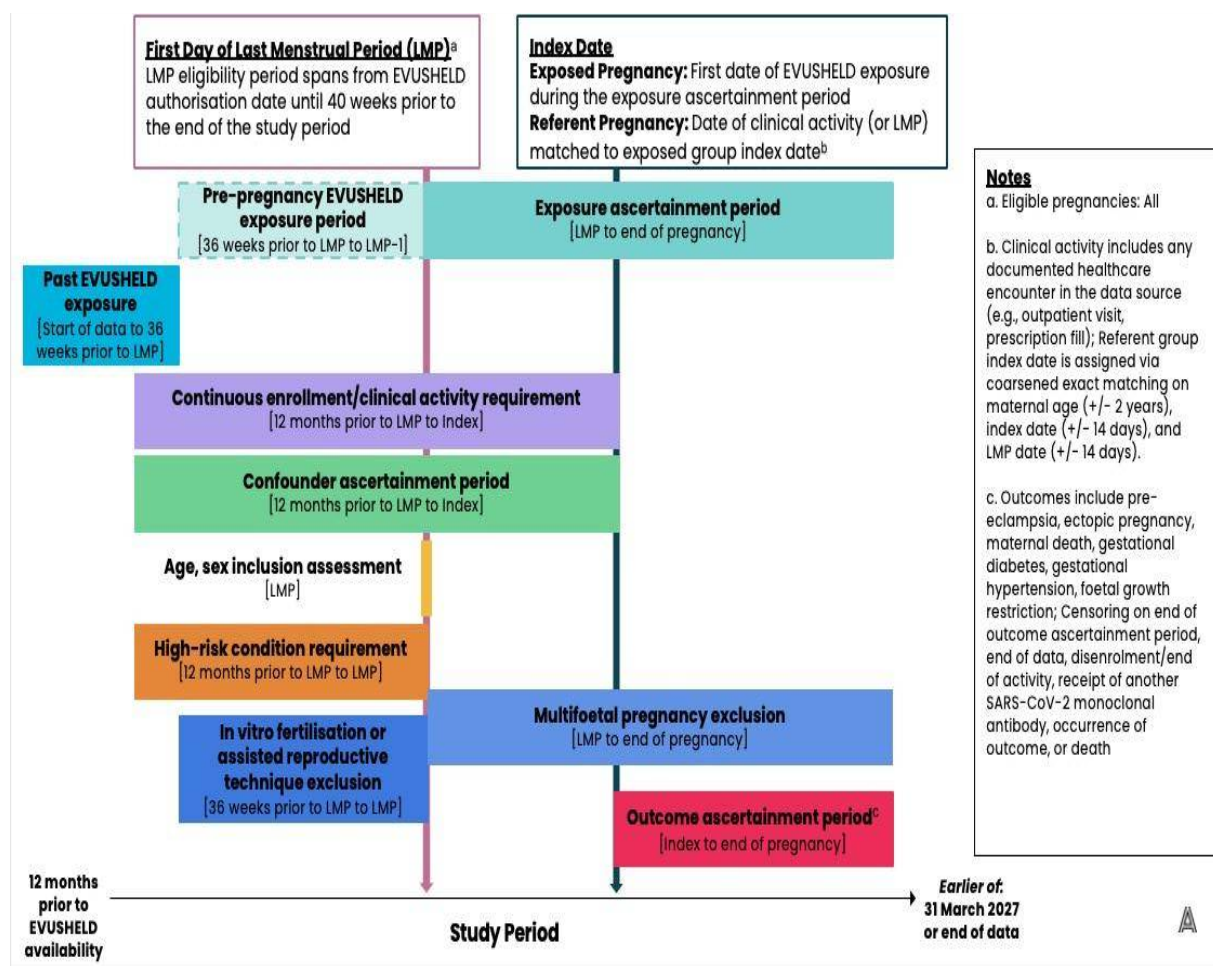


Figure 8 Analytic Cohort Design for Pregnancy Outcomes Potentially Associated with Exposure Anytime During Pregnancy and Measured After 20 Weeks Gestation

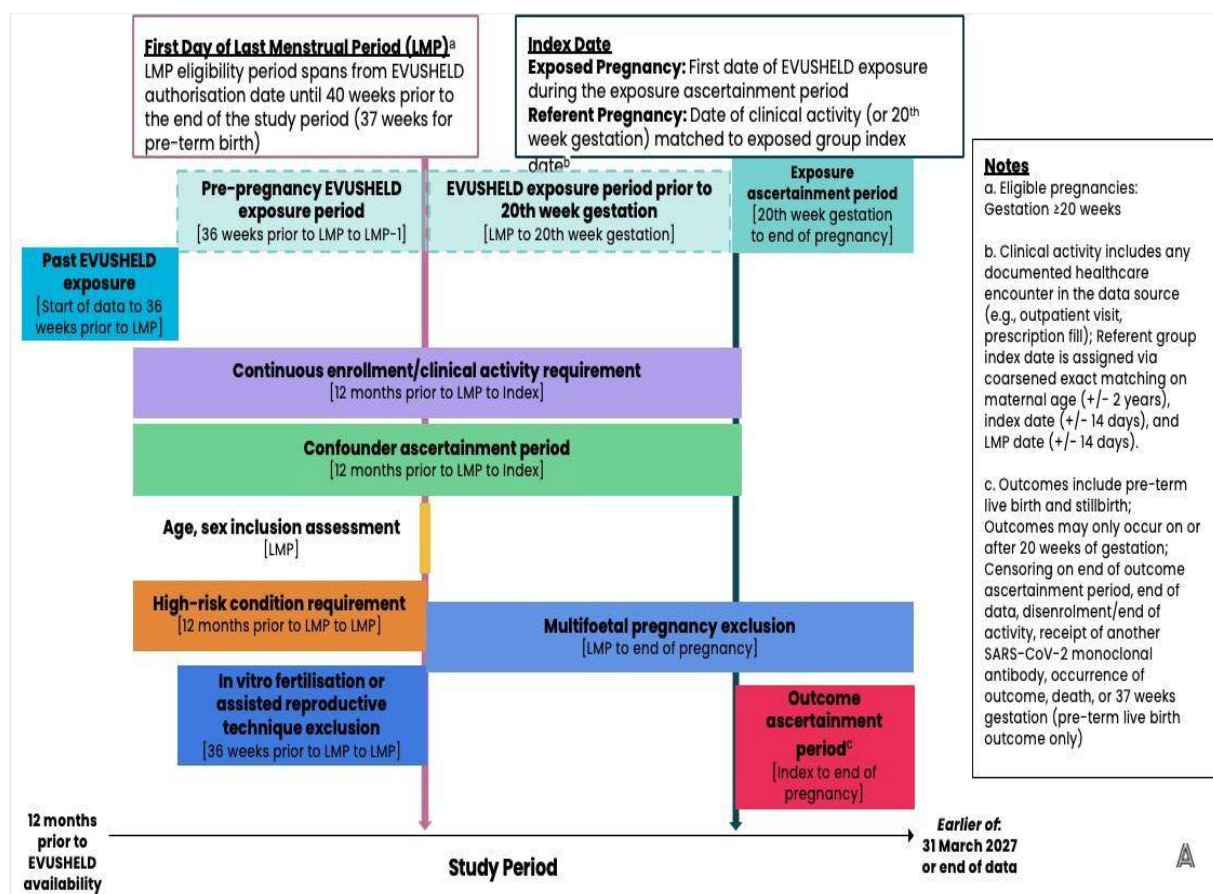
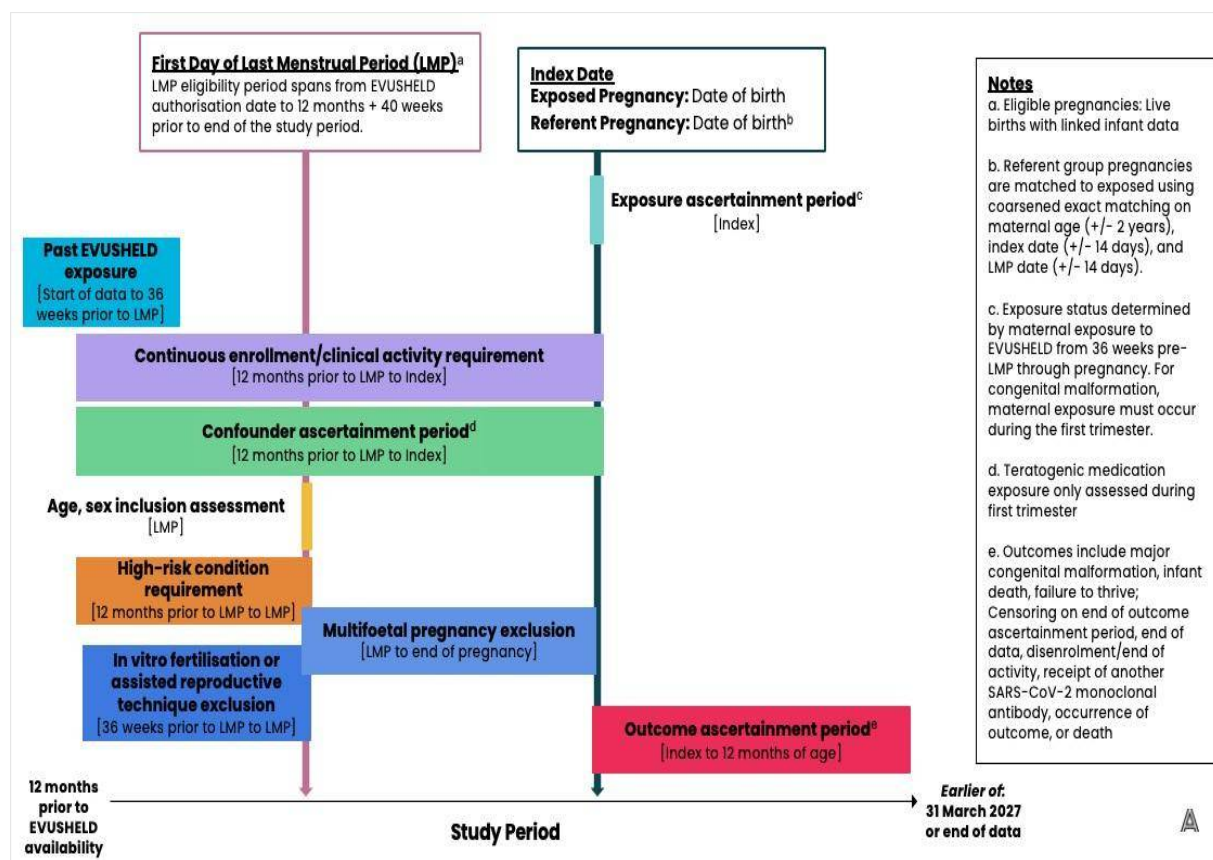


Figure 9 Analytic Cohort Design for Infant Outcomes



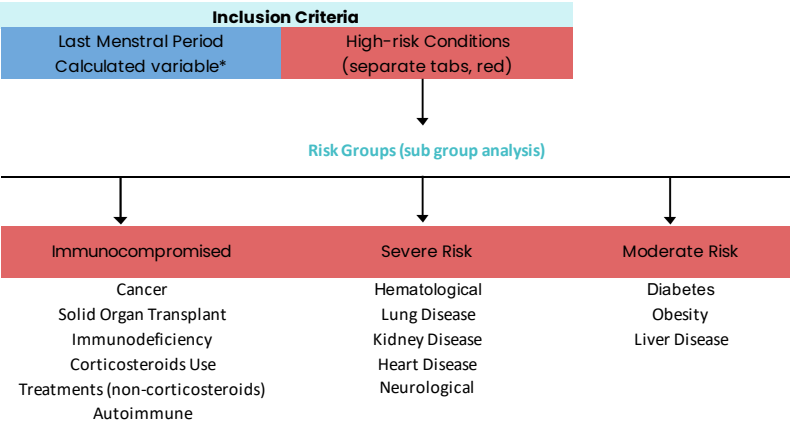
The pregnancy trimester definition by country is presented in [Table 13](#).

Table 13 Pregnancy Trimester Definition

Country	First trimester	Second trimester	Third Trimester
Canada (Bérard & Sheehy, 2014)	1st day of LMP-14 weeks	15 - 25 weeks	26 weeks - end of pregnancy
France (Bérard, 2019)	1st day of LMP-14 weeks	15 - 27 weeks	28 weeks - end of the pregnancy
United States (American College of Obstetricians and Gynecologists, 2020)	1st day of LMP-13 weeks	14 - 27 weeks	28 weeks - end of pregnancy

Annex 1: Code list

Patient Population Group Tabs	Patients diagnosed with a high-risk condition for which EVUSHELD is indicated and identification of pregnancy episode									
	Inclusion Criteria		Exclusion Criteria		Exposure	Outcomes			Covariates	
	Last Menstrual Period	High-risk Conditions	Multifetal pregnancies	IVF or Assited Reproductive Technology	EVUSHELD administration	Pregnancy	Neonatal	Infant	Pregnancy	Offspring



*please see instructions on LMP tab

Exclusion Criteria	
Multifetal pregnancies	IVF or Assisted Reproductive Technology

Code	Descriptor	Type	Encounter Type	Ascertainment Period	Measure	Source
Z3750	Multiple births, unspecified, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z372	Twins, both liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3750	Multiple births, unspecified, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3751	Triplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3752	Quadruplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3753	Quintuplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3754	Sextuplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3759	Other multiple births, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z373	Twins, one liveborn and one stillborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3760	Multiple births, unspecified, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3761	Triplets, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3762	Quadruplets, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3763	Quintuplets, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3764	Sextuplets, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z3769	Other multiple births, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Moll et al., 2022
Z37.2	Twins, both liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.3	Twins, one liveborn and one stillborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.4	Twins, both stillborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.5*	Other multiple births, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.50	Multiple births, unspecified, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.51	Triplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.52	Quadruplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.53	Quintuplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.54	Sextuplets, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.59	Other multiple births, all liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.6x	Other multiple births, some liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z37.7	Other multiple births, all stillborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.3x	Twin liveborn infant, born in hospital	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.4	Twin liveborn infant, born outside hospital	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.5	Twin liveborn infant, unspecified as to place of birth	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.6x	Other multiple liveborn infant, born in hospital	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.61	Triplet liveborn infant, delivered vaginally	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.62	Triplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.63	Quadruplet liveborn infant, delivered vaginally	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.64	Quadruplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.65	Quintuplet liveborn infant, delivered vaginally	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.66	Quintuplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.68	Other multiple liveborn infant, delivered vaginally	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.69	Other multiple liveborn infant, born outside hospital	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.7	Other multiple liveborn infant, born outside hospital	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
Z38.8	Other multiple liveborn infant, unspecified as to place of birth	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O30.0xx	Twin pregnancy	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O30.1xx	Triplet	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O30.2xx	Quadruplet	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O30.8xx	Other specified multiple gestation	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O30.9x	Multiple gestation, unspecified	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O31.xxxx	Complications specific to multiple gestation	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O32.xxxx	Maternal care for malpresentation of fetus	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O33.3xxx	Maternal care for disproportion due to outlet contraction	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O33.4xxx	Maternal care for disproportion of mixed maternal	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O33.5xxx	Maternal care for disproportion due to unusually	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O33.6xxx	Maternal care for disproportion due to hydrocephalus	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O33.7xxx	Maternal care for disproportion due to other fetal	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O35.xxxx	Maternal care for known or suspected fetal abnormality	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O36.xxxx	Maternal care for other fetal problems	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O40.xxxx	Polyhydramnios	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O41.xxxx	Other disorders of amniotic fluid and membranes	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O60.1xxx	Preterm labor with preterm delivery	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O60.2xxx	Term delivery with preterm labor	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O64.xxxx	Obstructed labor due to malposition and malpresentation	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
O69.xxxx	Labor and delivery complicated by umbilical cord	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Bertoia et al., 2022
V31.01c	Twin birth, mate liveborn, born in hospital, delivered	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V32.01c	Twin birth, mate stillborn, born in hospital, delivered	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V33.01c	Twin birth, unspecified whether mate liveborn or	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V34.01c	Other multiple birth (three or more), mates all live	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V35.01c	Other multiple birth (three or more), mates all still	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V36.01c	Other multiple birth (three or more), mates liveborn	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V37.01	Other multiple birth (three or more), unspecified	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
Z38.31	Twin liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
Z38.62	Triplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
Z38.64	Quadruplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
Z38.66	Quintuplet liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
Z38.69	Other multiple liveborn infant, delivered by cesarean	ICD-10-CM	Inpatient Adult Record	LMP to end of pregnanc	Multifoetal pregnancy	Murugappan, 2020
V23.85	Pregnancy resulting from assisted reproductive technology	ICD-9-CM	Inpatient Adult Record	Index	ART/IVF pregnancy	Johnston et al., 2015
58321	Artificial insemination; intracervical	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
58322	Artificial insemination; intrauterine	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54017	Incomplete cycle, treatment cancelled prior to start	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54020	In vitro fertilization procedure cancelled before a	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54021	In vitro fertilization procedure cancelled after aspiration	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89254	oocyte identification	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
58970	Follicle puncture for oocyte retrieval, any method	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
76948	Ultrasonic guidance for aspiration of ova	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54042	Management of ovulation induction (interpretation)	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89290	biopsy, embryo/oocyte for PGD, <=5 embryos	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89291	biopsy, embryo/oocyte for PGD, >5 embryos	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54015	Complete in-vitro fertilization cycle, not otherwise	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54011	In-vitro fertilization; including but not limited to	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89342	storage, embryos	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89255	Preparation of embryo for transfer	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
58974	Embryo transfer, intrauterine	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89250	Culture of oocyte(s)/embryo(s), <4 days	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89251	Culture of oocyte(s)/embryo(s), <4 day; with co-culture	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89268	Insemination of oocyte (for conventional IVF)	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89272	Extended culture of oocyte(s)/embryo(s), 4-7 day	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89354	thawing of cryopreserved; reproductive tissue, testis	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89356	thawing of cryopreserved; oocytes, each aliquot	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54037	Cryopreserved embryo transfer, case rate	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89352	Thawing of cryopreserved; embryos	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89258	Cryopreservation; embryo(s)	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54016	Frozen in-vitro fertilization cycle, case rate	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54018	Frozen embryo transfer procedure cancelled before	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
54022	Assisted oocyte fertilization, case rate	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2022
89280	Assisted oocyte fertilization, microtechniques, <4	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2023
89281	Assisted oocyte fertilization, microtechniques, >4	CPT	Inpatient/Outpatient Adult	Index	ART/IVF pregnancy	Chiu et al., 2024

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
C00.x	Malignant neoplasm of lip	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C01.x	Malignant neoplasm of base of tongue	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C02.x	Malignant neoplasm of other and unspecified parts	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C03.x	Malignant neoplasm of gum	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C04.x	Malignant neoplasm of floor of mouth	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C05.x	Malignant neoplasm of palate	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C06.x	Malignant neoplasm of other and unspecified parts	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C07.x	Malignant neoplasm of parotid gland	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C08.x	Malignant neoplasm of other and unspecified major salivary glands	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C09.x	Malignant neoplasm of tonsil	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C10.x	Malignant neoplasm of oropharynx	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C11.x	Malignant neoplasm of nasopharynx	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C12.x	Malignant neoplasm of pyriform sinus	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C13.x	Malignant neoplasm of hypopharynx	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C14.x	Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C15.x	Malignant neoplasm of oesophagus	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C16.x	Malignant neoplasm of stomach	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C17.x	Malignant neoplasm of small intestine	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C18.x	Malignant neoplasm of colon	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C19.x	Malignant neoplasm of rectosigmoid junction	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C20.x	Malignant neoplasm of rectum	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C21.x	Malignant neoplasm of anus and anal canal	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C22.x	Malignant neoplasm of liver and intrahepatic bile duct	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C23.x	Malignant neoplasm of gallbladder	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C24.x	Malignant neoplasm of other and unspecified parts of biliary tract	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C25.x	Malignant neoplasm of pancreas	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C26.x	Malignant neoplasm of other and ill-defined digest	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C30.x	Malignant neoplasm of nasal cavity and middle ear	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C31.x	Malignant neoplasm of accessory sinuses	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C32.x	Malignant neoplasm of larynx	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C33.x	Malignant neoplasm of trachea	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C34.x	Malignant neoplasm of bronchus and lung	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C37.x	Malignant neoplasm of thymus	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C38.x	Malignant neoplasm of heart, mediastinum and pleura	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C39.x	Malignant neoplasm of other and ill-defined sites in the respiratory system and pleura	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C40.x	Malignant neoplasm of bone and articular cartilage	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C41.x	Malignant neoplasm of bone and articular cartilage of other and unspecified	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C43.x	Malignant melanoma of skin	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C45.x	Mesothelioma	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C46.x	Kaposi's sarcoma	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C47.x	Malignant neoplasm of peripheral nerves and autonomic nervous system	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C48.x	Malignant neoplasm of retroperitoneum and peritoneum	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C49.x	Malignant neoplasm of other connective and soft tissue	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C50.x	Malignant neoplasm of breast	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C51.x	Malignant neoplasm of vulva	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C52.x	Malignant neoplasm of vagina	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C53.x	Malignant neoplasm of cervix uteri	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C54.x	Malignant neoplasm of corpus uteri	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C55.x	Malignant neoplasm of uterus, part unspecified	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C56.x	Malignant neoplasm of ovary	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C57.x	Malignant neoplasm of other and unspecified female genital organs	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C58.x	Malignant neoplasm of placenta	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C60.x	Malignant neoplasm of penis	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C61.x	Malignant neoplasm of prostate	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C62.x	Malignant neoplasm of testis	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C63.x	Malignant neoplasm of other and unspecified male genital organs	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C64.x	Malignant neoplasm of kidney, except renal pelvis	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C65.x	Malignant neoplasm of renal pelvis	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C66.x	Malignant neoplasm of ureter	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C67.x	Malignant neoplasm of bladder	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C68.x	Malignant neoplasm of other and unspecified urinary organs	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C69.x	Malignant neoplasm of eye and adnexa	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C70.x	Malignant neoplasm of meninges	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C71.x	Malignant neoplasm of brain	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C72.x	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C73.x	Malignant neoplasm of thyroid gland	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C74.x	Malignant neoplasm of adrenal gland	ICD-10-CM	Inpatient or Outpatient Adult record	Inclusion Criteria	Immunocompromised	Baseline	AstraZeneca
C75.x	Malignant neo other endocrine glands and related structures	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C76.x	Malignant neoplasm of other and ill-defined sites	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C77.x	Secondary and unspecified malignant neoplasm of lymph nodes	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C78.x	Secondary malignant neoplasm of respiratory and digestive organs	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C79.x	Secondary malignant neoplasm of other and unspecified sites	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C80.x	Malignant neoplasm without specification of site	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C81.x	Hodgkin's disease	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C82.x	Follicular [nodular] non-Hodgkin's lymphoma	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C88.x	Malignant immunoproliferative diseases	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C90.x	Multiple myeloma and malignant plasma cell neoplasm	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C97.x	Malignant neoplasms of independent (primary) multi	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C83.x	Diffuse non-Hodgkin's lymphoma	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C84.x	Peripheral and cutaneous T-cell lymphomas	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C85.x	Other and unspecified types of non-Hodgkin's lymph	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C86.x	Other specified types of T/NK-cell lymphoma	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C91.x	Lymphoid leukaemia	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C92.x	Myeloid leukaemia	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C93.x	Monocytic leukaemia	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C94.x	Other leukaemias of specified cell type	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
C95.x	Leukaemia of unspecified cell type	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca
D45.x	Polycythemia vera	ICD-10-CM	Inpatient or Outpatient Adult record	Cancer	Immunocompromised	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
Z94.0	Kidney transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.1	Heart transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.2	Lung transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.3	Heart and lungs transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.4	Liver transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.5	Skin transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.6	Bone transplant status	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.9	Transplanted organ and tissue status, unspecified	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
T86.x	Failure and rejection of transplanted organ and tissues	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca
Z94.8	Other transplanted organ and tissue status (inc. bone marr	ICD-10-CM	Inpatient/Outpatient Adult re	Organ transplant	Immunocompromised	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
B21.x	Human immunodeficiency virus [HIV] disease resulting in malignant neoplasr	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
B22.x	Human immunodeficiency virus [HIV] disease resulting in other specified dise	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
B23.x	Human immunodeficiency virus [HIV] disease resulting in other conditions	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
B24.x	Unspecified human immunodeficiency virus [HIV] disease	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D71.x	Functional disorders of polymorphonuclear neutrophils	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D80.x	Immunodeficiency with predominantly antibody defects [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D81.x	Combined immunodeficiencies [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D82.x	Immunodeficiency associated with other major defects [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D83.x	Common variable immunodeficiency [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D84.x	Other immunodeficiencies [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D89.x	Other disorders involving the immune mechanism, not elsewhere classified [I	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D80.x	Immunodeficiency with predominatly antibody defects	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D81.x	Combined immunodeficiencies	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D82.x	Immunodeficiency associated with other major defects	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D83.x	Common variable immunodeficiency	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D84.x	Other immunodeficiencies	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D89.x	Other disorders involving immune mechanism, not elsewhere classified	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca
D71.x	Functional disorders of polymorphonuclear neutrophils	ICD-10-CM	Inpatient/Outpatient Adult record	Organ Transplant	Immunocompromised	Baseline	AstraZeneca

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Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
D51.0	Pernicious anemia	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
D59.1	Autoimmune hemolytic anemia	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
D69.3	Idiopathic thrombocytopenic purpura	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
E05.0	Thyrotoxicosis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
E06.3	Autoimmune thyroiditis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
E10.x	Type 1 diabetes	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
E27.1	Primary adrenocortical insufficiency	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
G35.x	Multiple sclerosis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
G61.0	Guillain–Barre syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
G70.0	Myasthenia gravis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
H20.x	Iridocyclitis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
K50.x	Crohn's disease	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
K51.x	Ulcerative colitis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
K73.x	Autoimmune hepatitis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
K74.3	Primary biliary cirrhosis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
K90.0	Celiac disease	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
L10.x	Pemphigus	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
L12.x	Pemphigoid	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
L40.x	Psoriasis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
L63.x	Alopecia areata	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
L80.x	Vitiligo	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M05.x	Seropositive rheumatoid arthritis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M06.x	Other rheumatoid arthritis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M08.x	Juvenile arthritis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M31.3	Wegener's granulomatosis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M31.5	Giant cell arteritis with polymyalgia rhe	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M31.6	Other giant cell arteritis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M32.x	Systemic lupus erythematosus	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M33.x	Dermatopolymyositis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M34.x	Systemic sclerosis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M35.0	Sjogren's syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M35.3	Polymyalgia rheumatica	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca
M45.9	Ankylosing spondylitis	ICD-10-CM	Inpatient/Outpatient Adult record	Autoimmune Disease	Immunocompromised	Baseline	Astrazeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Period	Source
D57 .x	Sickle-cell disorders	ICD-10-CM	Inpatient/Outpatient Adult record	Hematological Disease	Severe risk	Baseline	Astrazeneca

Original Descriptor from compiled high-risk condition list: chronic lung disease (chronic bronchitis, COPD, cystic fibrosis, emphysema with dyspnoea on exertion, severe asthma), moderate to severe

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
J45.x	Asthma	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J46.x	Status asthmaticus	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J43.x	Emphysema	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J44.x	Other chronic obstructive pulmonary disease	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
CA22.x	Chronic obstructive pulmonary disease	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J40.x	Bronchitis, not specified as acute or chronic	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J41.x	Simple and mucopurulent chronic bronchitis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J42.x	Unspecified chronic bronchitis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J43.x	Emphysema	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J44.x	Other chronic obstructive pulmonary disease	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J45.x	Asthma	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J46.x	Status asthmaticus	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J47.x	Bronchiectasis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J60.x	Coalworker pneumoconiosis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J61.x	Pneumoconiosis due to asbestos and other mineral fibres	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J62.x	Pneumoconiosis due to dust containing silica	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J63.x	Pneumoconiosis due to other inorganic dusts	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J64.x	Unspecified pneumoconiosis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J65.x	Pneumoconiosis associated with tuberculosis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J66.x	Airway disease due to specific organic dust	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J67.x	Hypersensitivity pneumonitis due to organic dust	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J68.4	Chronic respiratory conditions due to chemicals, gases, fumes	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J70.1	Chronic and other pulmonary manifestations due to radiation	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J70.3	Chronic drug-induced interstitial lung disorders	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J84.1	Other interstitial pulmonary diseases with fibrosis	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J92.0	Pleural plaque with presence of asbestos	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J96.1	Chronic respiratory failure	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J98.2	Interstitial emphysema	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca
J98.3	Compensatory emphysema	ICD-10-CM	Inpatient/Outpatient Adult record	Lung Diseases	Severe	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
I12.x	Hypertensive renal disease	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
I13.x	Hypertensive heart and renal disease	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N00.x	Acute nephritic syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N01.x	Rapidly progressive nephritic syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N02.x	Recurrent and persistent haematuria	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N03.x	Chronic nephritic syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N04.x	Nephrotic syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N05.x	Unspecified nephritic syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N07.x	Hereditary nephropathy, not elsewhere clas	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N11.x	Chronic tubulo-interstitial nephritis	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N14.x	Drug- and heavy-metal-induced tubulo-inte	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N17.x	Acute renal failure	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N18.x	Chronic kidney disease	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N19.x	Unspecified kidney failure	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
Q61.x	Cystic kidney disease	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
N18.5	Chronic kidney disease stage 5	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
Z99.2	Dependence on renal dialysis	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
Y84.1	Kidney dialysis	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
Z49.1	Extracorporeal dialysis	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca
Z49.2	Other dialysis: Peritoneal dialysis	ICD-10-CM	Inpatient/Outpatient Adult record	Kidney disease	Severe	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
I21.x	Acute myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I22.x	Subsequent myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.x	Certain current complications following acute myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I11.0	Hypertensive heart disease with (congestive) heart failure	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I13.0	Hypertensive heart and renal disease with (congestive) heart failure	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I13.2	Hypertensive heart and renal disease with both (congestive) heart failure and renal	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I42.x	Cardiomyopathy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I50.x	Heart failure	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A52.0	Cardiovascular and cerebrovascular syphilis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A52.00	Cardiovascular syphilis, unspecified	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A52.05	Other cerebrovascular syphilis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A52.06	Other syphilitic heart involvement	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A52.09	Other cardiovascular syphilis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
A54.83	Gonococcal heart infection	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
B33.24	Viral cardiomyopathy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
B57.2	Chagas' disease (chronic) with heart involvement	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
C45.2	Mesothelioma of pericardium	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
D18.02	Hemangioma of intracranial structures	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
D69.0	Allergic purpura	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
E88.41	MELAS syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
G46.x	G46 Vascular syndromes of brain in cerebrovascular diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
G93.2	Benign intracranial hypertension	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
H31.3	Choroidal hemorrhage and rupture [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I01.0	Acute rheumatic pericarditis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I01.8	Other acute rheumatic heart disease	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I01.9	Acute rheumatic heart disease, unspecified	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I02.0	Rheumatic chorea with heart involvement	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I05.x	I05 Rheumatic mitral valve diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I06.x	I06 Rheumatic aortic valve diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I07.x	I07 Rheumatic tricuspid valve diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I08.x	I08 Multiple valve diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I09.x	I09 Other rheumatic heart diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I10.x	Essential (primary) hypertension	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I11.x	Hypertensive heart disease [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I15.x	I15 Secondary hypertension [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I20.x	I20 Angina pectoris [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.0	Hemopericardium as current complication following acute myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.1	Atrial septal defect as current complication following acute myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.2	Ventricular septal defect as current complication following acute myocardial infarction	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.3	Rupture of cardiac wall without hemopericardium as current complication follow	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.4	Rupture of chordae tendineae as current complication following acute myocardia	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I23.7	Postinfarction angina	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I25.11	I25.11 Atherosclerotic heart disease of native coronary artery with angina pectori	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I25.5	Ischemic cardiomyopathy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I25.7	I25.7 Atherosclerosis of coronary artery bypass graft(s) and coronary artery of tran	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pe	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I27.x	I27 Other pulmonary heart diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I28.x	I28 Other diseases of pulmonary vessels [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I31.x	I31 Other diseases of pericardium [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I32.x	Pericarditis in diseases classified elsewhere	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I34.x	I34 Nonrheumatic mitral valve disorders [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I35.x	I35 Nonrheumatic aortic valve disorders [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I36.x	I36 Nonrheumatic tricuspid valve disorders [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I37.x	I37 Nonrheumatic pulmonary valve disorders [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I42.x	I42 Cardiomyopathy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I43.x	Cardiomyopathy in diseases classified elsewhere	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I44.x	I44 Atrioventricular and left bundle-branch block [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.2	Bifascicular block	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.4	Nonspecific intraventricular block	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.5	Other specified heart block	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.6	Pre-excitation syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.8	I45.8 Other specified conduction disorders [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.81	Long QT syndrome	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.89	Other specified conduction disorders	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I45.9	Conduction disorder, unspecified	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I46.x	I46 Cardiac arrest [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I47.0	Re-entry ventricular arrhythmia	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I47.1	Supraventricular tachycardia	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I47.2	Ventricular tachycardia	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I48.3	Typical atrial flutter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I48.4	Atypical atrial flutter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I48.92	Unspecified atrial flutter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I49.x	I49 Other cardiac arrhythmias [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I50.x	I50 Heart failure [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I51.x	I51 Complications and ill-defined descriptions of heart disease [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I52.x	Other heart disorders in diseases classified elsewhere	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I63.02	Cerebral infarction due to thrombosis of basilar artery	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I63.12	Cerebral infarction due to embolism of basilar artery	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar artery	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I65.1	Occlusion and stenosis of basilar artery	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I67.x	I67 Other cerebrovascular diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I68.x	I68 Cerebrovascular disorders in diseases classified elsewhere [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I70.x	I70 Atherosclerosis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I72.x	I72 Other aneurysm [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I73.x	I73 Other peripheral vascular diseases [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I74.x	I74 Arterial embolism and thrombosis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I75.x	I75 Atheroembolism [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I76.x	Septic arterial embolism	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I77.x	I77 Other disorders of arteries and arterioles [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I78.x	I78 Diseases of capillaries [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I79.x	I79 Disorders of arteries, arterioles and capillaries in diseases classified elsewhere	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I80.x	I80 Phlebitis and thrombophlebitis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I82.x	I82 Other venous embolism and thrombosis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I87.x	I87 Other disorders of veins [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I95.x	I95 Hypotension [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I97.x	I97 Intraoperative and postprocedural complications and disorders of circulatory	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
I99.x	I99 Other and unspecified disorders of circulatory system [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K31.811	Angiodysplasia of stomach and duodenum with bleeding	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K31.819	Angiodysplasia of stomach and duodenum without bleeding	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K31.82	Dieulafoy lesion (hemorrhagic) of stomach and duodenum	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K55.x	K55 Vascular disorders of intestine [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K63.81	Dieulafoy lesion of intestine	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca

K76.3	Infarction of liver	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K76.4	Peliosis hepatis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
K76.5	Hepatic veno-occlusive disease	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
M05.3	M05.3 Rheumatoid heart disease with rheumatoid arthritis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
M30.x	M30 Polyarteritis nodosa and related conditions [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
M31.x	M31 Other necrotizing vasculopathies [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
N26.2	Page kidney	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
N26.9	Renal sclerosis, unspecified	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
N28.0	Ischemia and infarction of kidney	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O03.2	Embolism following incomplete spontaneous abortion	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O03.36	Cardiac arrest following incomplete spontaneous abortion	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O03.7	Embolism following complete or unspecified spontaneous abortion	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O03.86	Cardiac arrest following complete or unspecified spontaneous abortion	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O04.86	Cardiac arrest following (induced) termination of pregnancy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O07.2	Embolism following failed attempted termination of pregnancy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O07.36	Cardiac arrest following failed attempted termination of pregnancy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O08.2	Embolism following ectopic and molar pregnancy	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O10.x	O10 Pre-existing hypertension complicating pregnancy, childbirth and the puerperium	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O11.x	O11 Pre-existing hypertension with pre-eclampsia [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O13.x	O13 Gestational [pregnancy-induced] hypertension without significant proteinuria	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O14.x	O14 Pre-eclampsia [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O15.0	O15.0 Eclampsia complicating pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O16.x	O16 Unspecified maternal hypertension [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.2	O22.2 Superficial thrombophlebitis in pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.3	O22.3 Deep phlebotrombosis in pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.51	Cerebral venous thrombosis in pregnancy, first trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.52	Cerebral venous thrombosis in pregnancy, second trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.53	Cerebral venous thrombosis in pregnancy, third trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.8	O22.8 Other venous complications in pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O22.9	O22.9 Venous complication in pregnancy, unspecified [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O26.5	O26.5 Maternal hypotension syndrome [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O29.19	O29.19 Other cardiac complications of anesthesia during pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O69.5	O69.5 Labor and delivery complicated by vascular lesion of cord [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O74.2	Cardiac complications of anesthesia during labor and delivery	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O86.81	Puerperal septic thrombophlebitis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O87.x	O87 Venous complications and hemorrhoids in the puerperium [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.0	O88.0 Obstetric air embolism [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.2	O88.2 Obstetric thromboembolism [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.31	O88.31 Pyemic and septic embolism in pregnancy [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.32	Pyemic and septic embolism in childbirth	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.33	Pyemic and septic embolism in the puerperium	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O88.8	O88.8 Other obstetric embolism [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.411	Diseases of the circulatory system complicating pregnancy, first trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.412	Diseases of the circulatory system complicating pregnancy, second trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.413	Diseases of the circulatory system complicating pregnancy, third trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.419	Diseases of the circulatory system complicating pregnancy, unspecified trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.42	Diseases of the circulatory system complicating childbirth	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
O99.43	Diseases of the circulatory system complicating the puerperium	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
P29.x	P29 Cardiovascular disorders originating in the perinatal period [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q20.x	Q20 Congenital malformations of cardiac chambers and connections [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q21.x	Q21 Congenital malformations of cardiac septa [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q23.x	Q23 Congenital malformations of aortic and mitral valves [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q24.x	Q24 Other congenital malformations of heart [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q27.x	Q27 Other congenital malformations of peripheral vascular system [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Q28.x	Q28 Other congenital malformations of circulatory system [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
R09.89	Other specified symptoms and signs involving the circulatory and respiratory systems	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
R55.x	Syncope and collapse	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
R57.0	Cardiogenic shock	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S09.0	S09.0 Injury of blood vessels of head, not elsewhere classified [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S15.x	S15 Injury of blood vessels at neck level [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S25.x	S25 Injury of blood vessels of thorax [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S45.x	S45 Injury of blood vessels at shoulder and upper arm level [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S55.x	S55 Injury of blood vessels at forearm level [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
S65.x	S65 Injury of blood vessels at wrist and hand level [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T67.1	T67.1 Heat syncope [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T79.0	T79.0 Air embolism (traumatic) [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T79.1	T79.1 Fat embolism (traumatic) [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T79.6	T79.6 Traumatic ischemia of muscle [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T80.OXXA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T80.OXXD	Air embolism following infusion, transfusion and therapeutic injection, subsequent encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T80.1XXA	Vascular complications following infusion, transfusion and therapeutic injection, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T80.1XXD	Vascular complications following infusion, transfusion and therapeutic injection, subsequent encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.11	T81.11 Postprocedural cardiogenic shock [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.710A	Complication of mesenteric artery following a procedure, not elsewhere classified, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.711A	Complication of renal artery following a procedure, not elsewhere classified, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.718A	Complication of other artery following a procedure, not elsewhere classified, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.719A	Complication of unspecified artery following a procedure, not elsewhere classified, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T81.72XA	Complication of vein following a procedure, not elsewhere classified, initial encounter	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.0	T82.0 Mechanical complication of heart valve prosthesis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.3	Mechanical complication of other vascular grafts	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.6	T82.6 Infection and inflammatory reaction due to cardiac valve prosthesis [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.818	T82.818 Embolism due to vascular prosthetic devices, implants and grafts [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.838	T82.838 Hemorrhage due to vascular prosthetic devices, implants and grafts [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.858	T82.858 Stenosis of other vascular prosthetic devices, implants and grafts [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.867	T82.867 Thrombosis due to cardiac prosthetic devices, implants and grafts [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T82.868	T82.868 Thrombosis due to vascular prosthetic devices, implants and grafts [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.2	T86.2 Complications of heart transplant [Non-Specific Code]	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.3	Heart-lung transplant failure and rejection	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.711	Personal history of pulmonary embolism	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.718	Personal history of other venous thrombosis and embolism	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.72	Personal history of thrombophlebitis	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.74	Personal history of sudden cardiac arrest	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T86.79	Personal history of other diseases of the circulatory system	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
T87.4	Personal history of (corrected) congenital malformations of heart and circulatory system	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z95.811	Presence of heart assist device	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z95.812	Presence of fully implantable artificial heart	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z20.x	Z20 Congenital malformations of cardiac chambers and connections	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z21.x	Z21 Congenital malformations of cardiac septa	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z23.x	Z23 Congenital malformations of aortic and mitral valves	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z24.x	Z24 Other congenital malformations of heart	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z27.x	Z27 Other congenital malformations of peripheral vascular system	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z28.x	Z28 Other congenital malformations of circulatory system	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system	ICD-10-CM	Inpatient/Outpatient Adult record	Heart Diseases	Severe	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
G35.x	Multiple sclerosis	ICD-10-CM	Inpatient/Outpatient Adult record	Neurological Disease	Severe	Baseline	AstraZeneca
G12.2	Motor neuron disease	ICD-10-CM	Inpatient/Outpatient Adult record	Neurological Disease	Severe	Baseline	AstraZeneca
G70.0	Myasthenia gravis	ICD-10-CM	Inpatient/Outpatient Adult record	Neurological Disease	Severe	Baseline	AstraZeneca
G10.x	Huntington's disease	ICD-10-CM	Inpatient/Outpatient Adult record	Neurological Disease	Severe	Baseline	AstraZeneca

Code	Descriptor	Type	Encounter Type	Measure	Risk group	Period	Source
E10.0.x	Insulin-dependent diabetes mellitus with coma	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.1.x	Insulin-dependent diabetes mellitus with ketoacidosis	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.9.x	Insulin-dependent diabetes mellitus without complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.0.x	Non-insulin-dependent diabetes mellitus with coma	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.1.x	Non-insulin-dependent diabetes mellitus with ketoacidosis	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.9.x	Non-insulin-dependent diabetes mellitus without complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.2.x	Insulin-dependent diabetes mellitus with renal complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.3.x	Insulin-dependent diabetes mellitus with ophthalmic complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.4.x	Insulin-dependent diabetes mellitus with neurological complication	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.5.x	Insulin-dependent diabetes mellitus with peripheral circulatory com	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.6.x	Insulin-dependent diabetes mellitus with other specified complicati	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.7.x	Insulin-dependent diabetes mellitus with multiple complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E10.8.x	Insulin-dependent diabetes mellitus with unspecified complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.2.x	Non-insulin-dependent diabetes mellitus with renal complications	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.3.x	Non-insulin-dependent diabetes mellitus with ophthalmic complica	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.4.x	Non-insulin-dependent diabetes mellitus with neurological complici	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.5.x	Non-insulin-dependent diabetes mellitus with peripheral circulatory	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.6.x	Non-insulin-dependent diabetes mellitus with other specified compl	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.7.x	Non-insulin-dependent diabetes mellitus with multiple complicatio	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
E11.8.x	Non-insulin-dependent diabetes mellitus with unspecified complical	ICD-10-CM	Inpatient/Outpatient Adult record	Diabetes	Moderate risk of COVID-19 disease progression	Baseline	Astrazeneca
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypog	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypog	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypc	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel
O24.434	Gestational diabetes mellitus in the puerperium, insulin controlled	ICD-10-CM	Inpatient/Outpatient Adult record	Gestational diabetes required medication for control	Severe		Sentinel

Code	Descriptor	Type	Encounter Type	Risk Group	Measure	Evaluation Period	Source
E66.0.x	Obesity due to excess calories	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.01	Morbid (severe) obesity due to excess calories	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.09	Other obesity due to excess calories	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.1	Drug induced obesity	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.2	Morbid (severe) obesity with alveolar hypoventilation	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.8	Other obesity	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
E66.9	Obesity unspecified	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.211	Obesity complicating pregnancy, first trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.212	Obesity complicating pregnancy, second trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.213	Obesity complicating pregnancy, third trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.215	Obesity complicating the puerperium	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.30	Body mass index [BMI] 30.0-30.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.31	Body mass index [BMI] 31.0-31.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.32	Body mass index [BMI] 32.0-32.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.33	Body mass index [BMI] 33.0-33.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.34	Body mass index [BMI] 34.0-34.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.35	Body mass index [BMI] 35.0-35.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.36	Body mass index [BMI] 36.0-36.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.37	Body mass index [BMI] 37.0-37.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.38	Body mass index [BMI] 38.0-38.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.39	Body mass index [BMI] 39.0-39.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.41	Body mass index [BMI] 40.0-44.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.42	Body mass index [BMI] 45.0-49.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.43	Body mass index [BMI] 50.0-59.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.44	Body mass index [BMI] 60.0-69.9, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
Z68.45	Body mass index [BMI] 70 or greater, adult	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.210	Obesity complicating pregnancy, unspecified trimester	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library
O99.214	Obesity complicating childbirth	ICD-10-CM	Inpatient/Outpatient Adult record	Moderate	Moderate risk of COVID-19 disease progression	Index	Aetion Measure Library

Code	Descriptor	Type	Encounter Type	Measure	Risk Group	Ascertainment Period	Source
B15.0	Hepatitis A with hepatic coma	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
B16.0	Acute hepatitis B with delta-agent (coinfection) with h	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
B16.2	Acute hepatitis B without delta-agent with hepatic cor	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
B19.0	Unspecified viral hepatitis with hepatic coma	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
I85.x	Oesophageal varices	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
K70.4	Alcoholic hepatic failure	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
K72.x	Hepatic failure, not elsewhere classified	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca
K76.6	Portal hypertension	ICD-10-CM	Inpatient/Outpatient Adult record	Liver Diseases	Moderate risk of COVID-19 disease progression	Baseline	AstraZeneca

Generic Name	Code	Code Type	Encounter Type	Descriptor	Measure	Evaluation Period	Source
tixagevimab	0310-8895-01	NDC	Inpatient/Outpatient/Pharmacy	mAb	Exposure	Index	Evusheld.com
cilgavimab	0310-1061-01	NDC	Inpatient/Outpatient/Pharmacy	mAb	Exposure	Index	Evusheld.com
tixagevimab and cilgavimab	J06BD03	ATC	Inpatient/Outpatient/Pharmacy	mAb	Exposure	Index	WHOCC
NA	Q0220	HCPCS	Inpatient/Outpatient/Pharmacy	Injection (300mg dose)	Exposure	Index	Evusheld.com
NA	Q0221	HCPCS	Inpatient/Outpatient/Pharmacy	Injection (600mg dose)	Exposure	Index	Evusheld.com
NA	Z23	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Encounter for immunization	Exposure	Index	Evusheld.com
NA	Z28.310	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Unvaccinated for COVID-19	Exposure	Index	Evusheld.com
NA	Z28.311	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Partially vaccinated for COVID-19	Exposure	Index	Evusheld.com
NA	Z28.39	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Other under-immunization status	Exposure	Index	Evusheld.com
NA	Z29.8	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Encounter for other specified prophylactic measures	Exposure	Index	Evusheld.com
NA	Z41.8	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Encounter for other procedures for purposes other than remedying health state	Exposure	Index	Evusheld.com
NA	Z28.04	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Immunization not carried out because of patient allergy to vaccine or component	Exposure	Index	Evusheld.com
NA	Z28.09	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Immunization not carried out because of other contraindication	Exposure	Index	Evusheld.com
NA	Z88.7	ICD-10-CM	Inpatient/Outpatient/Pharmacy	Allergy status to serum and vaccine	Exposure	Index	Evusheld.com

Source	Measure	Encounter Type	Type	Descriptor
Molli 2021	Spontaneous Abortion	Spontaneous Abortion - Adult	ICD-10-CM	Spontaneous abortion
Molli 2021	Spontaneous Abortion	Spontaneous Abortion - Adult	ICD-10-CM	Missed abortion
Molli 2021	Spontaneous Abortion	Spontaneous Abortion	HCPCS	Anesthesia for missed abortion
Molli 2021	Spontaneous Abortion	Spontaneous Abortion	HCPCS	Treatment of incomplete abortion, any trimester, completed surgically
Molli 2021	Spontaneous Abortion	Spontaneous Abortion	HCPCS	Treatment of missed abortion, completed surgically, first trimester
Molli 2021	Spontaneous Abortion	Spontaneous Abortion	HCPCS	Treatment of missed abortion, completed surgically, second trimester
Molli 2021	Spontaneous Abortion	Spontaneous Abortion	HCPCS	Treatment of septic abortion, completed surgically
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm labor with preterm delivery, unspecified trimester
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm labor second trimester with preterm delivery second trimester
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm labor second trimester with preterm delivery third trimester
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm labor third trimester with preterm delivery third trimester
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm premature rupture of membranes, onset of labor within 24 hours
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm premature rupture of membranes, onset of labor > 24 hours later
Molli 2021	Preterm Birth	Preterm Birth - Adult or infant	ICD-10-CM	Preterm premature rupture of membranes, unspecified time
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia, unspecified trimester
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia, second trimester
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia, third trimester
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia complicating childbirth
Labgpid 2021	Preeclampsia	Preeclampsia	ICD-10-CM	Severe pre-eclampsia, complicating the puerperium
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Laparoscopy, surgical, with removal of adnexal structures (partial or total oophorectomy and/o
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Laparoscopy, surgical, with salpingostomy (salpingoneostomy)
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Salpingostomy (salpingoneostomy)
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	HCPCS	Methotrexate, oral, 2.5 mg
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	HCPCS	Methotrexate sodium, 5 mg
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	HCPCS	Methotrexate sodium, 50 mg
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Salpingostomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Salpingostomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Removal of both fallopian tubes at same operative episode
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Removal of remaining fallopian tube
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Excision or destruction of lesion of fallopian tube
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Bilateral partial salpingectomy, not otherwise specified
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Other (partial salpingectomy)
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Salpingo-oophorectomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Salpingo-salpingostomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Salpingectomy with removal of tubal pregnancy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Removal Of Extratubal Ectopic Pregnancy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-9-CM (procedure)	Surgical treatment of ectopic pregnancy, tubal or ovarian, requiring salpingectomy and/or oop
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Surgical treatment of ectopic pregnancy, tubal or ovarian, without salpingectomy and/or oop
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Surgical treatment of ectopic pregnancy, abdominal pregnancy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Surgical treatment of ectopic pregnancy, interstitial, uterine pregnancy requiring total hyster
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Surgical treatment of ectopic pregnancy, interstitial, uterine pregnancy with partial resecti
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Surgical treatment of ectopic pregnancy, cervical, with evacuation
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Laparoscopic treatment of ectopic pregnancy, without salpingectomy and/or oophorectomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	CPT	Laparoscopic treatment of ectopic pregnancy, with salpingectomy and/or oophorectomy
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-CM	Drainage of Right Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Drainage of Left Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Drainage of Bilateral Fallopian Tubes, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Right Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Right Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Right Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Right Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Right Fallopian Tube, Via Natural or Artificial Opening Endoscopic
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Left Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Left Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Left Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Left Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Left Fallopian Tube, Via Natural or Artificial Opening Endoscopic
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Bilateral Fallopian Tubes, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Bilateral Fallopian Tubes, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Bilateral Fallopian Tubes, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Bilateral Fallopian Tubes, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Extraction of Matter from Bilateral Fallopian Tubes, Via Natural or Artificial Opening Endoscopic
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Insertion of Other Device into Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Insertion of Other Device into Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Insertion of Other Device into Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Drainage Device from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Infusion Device from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Autologous Tissue Substitute from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Extraluminal Device from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Intraluminal Device from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Other Device from Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Drainage Device from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Infusion Device from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Autologous Tissue Substitute from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Extraluminal Device from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Intraluminal Device from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Other Device from Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Drainage Device from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Infusion Device from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Autologous Tissue Substitute from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Extraluminal Device from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Intraluminal Device from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Percutaneous Endoscopic Ap
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Other Device from Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Autologous Tissue Substitute from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Extraluminal Device from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Extraluminal Device from Fallopian Tube, Via Natural or Artificial Opening Endoscopic
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Intraluminal Device from Fallopian Tube, Via Natural or Artificial Opening Endoscopic
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Nonautologous Tissue Substitute from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Removal of Other Device from Fallopian Tube, Via Natural or Artificial Opening
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Open Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Extraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Intraluminal Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Synthetic Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Nonautologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Other Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Drainage Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Infusion Device in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 2018	Ectopic pregnancy	Ectopic pregnancy	ICD-10-PCS	Revision of Autologous Tissue Substitute in Fallopian Tube, Percutaneous Endoscopic Approach
Saravani 2020 Match 				

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Code	Descriptor	Type	Encounter Type	Measure	Ascertainment Period	Source
P22.x	Respiratory distress syndrome of newborn	ICD-10-CM	Inpatient Infant record	Neonatal Respiratory Distress Syndr	DOB	Bets 2021
656.5x	Fetal growth restriction	ICD-9-CM	Inpatient or other therapy cl	Small for Gestational Age (SGA)	DOB + 30 days	He 2020
764.0x	Small, smallness for dates, fetus or newborn	ICD-9-CM	Inpatient or other therapy cl	Small for Gestational Age (SGA)	DOB + 30 days	He 2020
764.1x	Small, smallness for dates, with malnutrition	ICD-9-CM	Inpatient or other therapy cl	Small for Gestational Age (SGA)	DOB + 30 days	He 2020
764.9x	Fetal growth retardation unspecified	ICD-9-CM	Inpatient or other therapy cl	Small for Gestational Age (SGA)	DOB + 30 days	He 2020
P0.7	Disorders related to short gestation and low birth weight, not elsewhere cla	ICD-10-CM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB + 7 days	WHO 2019
P07.0	Extremely low birth weight	ICD-10-CM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB + 7 days	WHO 2019
P07.1	Other low birth weight	ICD-10-CM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB + 7 days	WHO 2019
P07.x	Extremely low birth weight newborn, unspecified weight	ICD-10-PM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB until day 28 of life (inclusive)	WHO 2019
*Note: When both birth weight and gestational age are available, priority of assignment		ICD-10-CM	Inpatient/Outpatient Infant	LBW/SGA	DOB until day 28 of life (inclusive)	WHO 2019
N1	congenital malformations, deformations, and chromosomal abnormalities	ICD-10-PM	Inpatient/Outpatient Infant	Major Congenital Malformations	DOB until day 28 of life (inclusive)	WHO 2019
N2	disorders related to fetal growth	ICD-10-PM	Inpatient/Outpatient Infant	SGA	DOB until day 28 of life (inclusive)	WHO 2019
P05.1	Newborn small for gestational age	ICD-10-PM	Inpatient/Outpatient Infant	SGA	DOB until day 28 of life (inclusive)	WHO 2019
N2	disorders related to fetal growth	ICD-10-PM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB until day 28 of life (inclusive)	WHO 2019
N8	neonatal conditions	ICD-10-PM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB until day 28 of life (inclusive)	WHO 2019
N9	low birth weight and prematurity	ICD-10-PM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB until day 28 of life (inclusive)	WHO 2019
N11	neonatal death of unspecified cause	ICD-10-PM	Inpatient/Outpatient Infant	Low Birth Weight (LBW)	DOB until day 28 of life (inclusive)	WHO 2019
93.9	Noninvasive mechanical ventilation	ICD-9-CM	Inpatient/Outpatient Infant	Need for resuscitation	DOB until day 28 of life (inclusive)	ICD-9-CM
96.7	Continuous invasive mechanical ventilation	ICD-9-CM	Inpatient/Outpatient Infant	Need for resuscitation	DOB until day 28 of life (inclusive)	ICD-9-CM
99.6	Cardiopulmonary resuscitation	ICD-9-CM	Inpatient/Outpatient Infant	Need for resuscitation	DOB until day 28 of life (inclusive)	ICD-9-CM
96.04	Insertion of an endotracheal tube	ICD-9-CM	Inpatient/Outpatient Infant	Need for resuscitation	DOB until day 28 of life (inclusive)	ICD-9-CM
96.05	Other intubation of the respiratory tract	ICD-9-CM	Inpatient/Outpatient Infant	Need for resuscitation	DOB until day 28 of life (inclusive)	ICD-9-CM

Code	Descriptor	Type	Encounter Type	Measure	Ascertainment Period	Source
R62.8	Other lack of expected normal physiological development	ICD-10-CM	Inpatient/Outpatient Infant record	Failure to Thrive	28 days of birth until 12 months of age	Olsen 2002
E64.9	Sequelae of unspecified nutritional deficiency	ICD-10-CM	Inpatient/Outpatient Infant record	Failure to Thrive	28 days of birth until 12 months of age	Olsen 2002
E34.3	Short stature, not elsewhere classified	ICD-10-CM	Inpatient/Outpatient Infant record	Failure to Thrive	29 days of birth until 12 months of age	Olsen 2002
740.xx	Central Nervous System	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
741.xx	Spina bifida	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
742.xx	Other congenital anomalies of nervous system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
743.xx (exclude if only 743.6x and 743.8x)	Congenital anomalies of eye	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
745.xx (exclude if only 745.5 AND preterm, 746.02 AND pr Bulbus cordis anomalies and anomalies of cardiac septum)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
746.xx (exclude if only 745.5 AND preterm, 746.02 AND pr Other congenital anomalies of heart)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.0x (exclude if only 745.5 AND preterm, 746.02 AND pr Patent ductus arteriosus)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.1x (exclude if only 745.5 AND preterm, 746.02 AND pr Coarctation of aorta)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.2x (exclude if only 745.5 AND preterm, 746.02 AND pr Other congenital anomalies of aorta)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.3x (exclude if only 745.5 AND preterm, 746.02 AND pr Congenital anomalies of pulmonary artery)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.4x (exclude if only 745.5 AND preterm, 746.02 AND pr Congenital anomalies of great veins)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.83 (exclude if only 745.5 AND preterm, 746.02 AND pr Persistent fetal circulation)		ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.6x (exclude if only 747.83)	Other congenital anomalies of peripheral vascular system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.7x (exclude if only 747.83)	Hypoplastic left heart syndrome	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.8x (exclude if only 747.83)	Other specified congenital anomalies of circulatory system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
747.9x (exclude if only 747.83)	Unspecified anomaly of circulatory system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
748.xx (do not count if only 748.1x)	Congenital anomalies of respiratory system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
749.xx	Cleft palate and cleft lip	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
750.xx (do not count if only 750.0x, 750.1x, 750.50, 751.1x)	Other congenital anomalies of upper alimentary tract	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
751.xx (do not count if only 750.0x, 750.1x, 750.50, 751.1x)	Other congenital anomalies of digestive system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
752.xx (do not count if only 752.42, 752.52) (in addition, 752.81, 752.82, 752.83, 752.84, 752.85, 752.86, 752.87, 752.88, 752.89, 752.90, 752.91, 752.92, 752.93, 752.94, 752.95, 752.96, 752.97, 752.98, 752.99)	Congenital anomalies of genital organs	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
753.xx (do not include if only 753.7x)	Congenital anomalies of urinary system	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
754.xx (do not count if only 754.3x, 754.81, 754.82, 756.1x)	Certain congenital musculoskeletal deformities	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
755.xx (exclude if only 755.65)	Other congenital anomalies of limbs	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
756.xx (do not count if only 754.3x, 754.81, 754.82, 756.1x)	Other congenital musculoskeletal anomalies	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
757.xx (excluded if only 757.2-757.6, 759.81-759.83)	Congenital anomalies of the integument	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
758.xx (excluded if only 757.2-757.6, 759.81-759.83)	Chromosomal anomalies	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016
759.xx (excluded if only 757.2-757.6, 759.81-759.83)	Other and unspecified congenital anomalies	ICD-9-CM	Inpatient/Outpatient Infant record	Major Congenital Malformations	birth until 12 months of age	Paterno 2017 , Huybrechts 2016

Code	Descriptor	Type	Encounter Type	Measure	Ascertainment Period	Source
U07.1	COVID-19	ICD-10-CM	Medical Claims - Adult record	SARS-CoV-2 Infection	Index	WHO, 2022
Z3A.01	Less than 8 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.08	8 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.09	9 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.10	10 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.11	11 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.12	12 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.13	13 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.14	14 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.15	15 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.16	16 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.17	17 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.18	18 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.19	19 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.20	20 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.21	21 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.22	22 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.23	23 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.24	24 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.25	25 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.26	26 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.27	27 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.28	28 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.29	29 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.30	30 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.31	31 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.32	32 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.33	33 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.34	34 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.35	35 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.36	36 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.37	37 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.38	38 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.39	39 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.40	40 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.41	41 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
Z3A.42	42 weeks gestation of pregnancy	ICD-10	Medical Claims - Adult record	Gestational Age	Index date	Moll, 2021
74	Classical cesarean section, transperitoneal	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74	Classical cesarean section	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.1	Low cervical cesarean section	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.2	Extraperitoneal cesarean section	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.4	Cesarean section of other specified type	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.9	Cesarean section of unspecified type	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.9	Cesarean section of unspecified type	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.99	Other cesarean section of unspecified type	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
74.99	Other cesarean section of unspecified type	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
649.81	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks of gestation	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
649.82	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks of gestation	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
669.7	Cesarean delivery, without mention of indication, unspecified as to episode of care	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
669.71	Cesarean delivery, without mention of indication, delivered, with or without mention of indication	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
765	Cesarean section with cc/mcc	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
766	Cesarean section without cc/mcc	ICD-9-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery	CPT	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00020	Extraction of Products of Conception, Classical, Open Approach	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00021	Extraction of Products of Conception, Low Cervical, Open Approach	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00022	Extraction of Products of Conception, Extraperitoneal, Open Approach	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00723	Extraction of Products of Conception, Low Forceps, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00724	Extraction of Products of Conception, Mid Forceps, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00725	Extraction of Products of Conception, High Forceps, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00726	Extraction of Products of Conception, Vacuum, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00727	Extraction of Products of Conception, Internal Version, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
10D00728	Extraction of Products of Conception, Other, Via Natural or Artificial Opening	ICD-10-PCS	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
59510	Routine obstetric care and cesarean delivery	CPT	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
59618	Routine obstetric care, cesarean delivery after failed VBAC	CPT	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
075.82	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks of gestation	ICD-10-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
082	Encounter for cesarean delivery without indication	ICD-10-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
V30.01c	Single liveborn, born in hospital, delivered by cesarean section	ICD-10-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
V39.01c	Liveborn, unspecified whether single, twin or multiple, born in hospital, delivered by cesarean section	ICD-10-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
Z38.01	Single liveborn infant, delivered by cesarean	ICD-10-CM	Medical Claims - Adult record	C-section delivery	Index	Murugappan, 2020
A55	Chlamydial lymphogranuloma (venereum)	ICD-10-CM	Medical Claims - Adult record	Past Infections - Chlamydia	Index	Ho, 2021
A56	Other sexually transmitted chlamydial diseases	ICD-10-CM	Medical Claims - Adult record	Past Infections - Chlamydia	Index	Ho, 2021
A71	Trachoma	ICD-10-CM	Medical Claims - Adult record	Past Infections - Chlamydia	Index	Ho, 2021
A74.9	Chlamydial infection, unspecified	ICD-10-CM	Medical Claims - Adult record	Past Infections - Chlamydia	Index	Ho, 2021
F10.x	Alcohol related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F11.x	Opioid related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F12.x	Cannabis related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F13.x	Sedative, hypnotic, or anxiolytic related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F14.x	Cocaine related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F15.x	Other stimulant related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F16.x	Hallucinogen related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F18.x	Inhalant related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
F19.x	Other psychoactive substance related disorders	ICD-10-CM	Medical Claims - Adult record	Substance use (tobacco, alcohol, illicit drugs)	Index	Williams, 2022
O24.4	Gestational diabetes mellitus	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Gestational Diabetes	Index	Geiger, 2021
O99.81	Abnormal glucose complicating pregnancy, childbirth and the puerperium	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Gestational Diabetes	Index	Geiger, 2021
O13	Gestational [pregnancy induced] hypertension without significant proteinuria	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Gestational hypertension	Index	Geiger, 2021
O16	Unspecified maternal hypertension	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Gestational hypertension	Index	Geiger, 2021
E10.XX	Type 1 diabetes mellitus	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Type I and Type II diabetes	Index	Chi, 2019
E11.XX	Type 2 diabetes mellitus	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Type I and Type II diabetes	Index	Chi, 2019
B18.8	Other chronic viral hepatitis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
B18.9	Chronic viral hepatitis, unspecified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K70.0	Alcoholic fatty liver	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K75.9	Inflammatory liver disease, unspecified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
B18.0	Chronic viral hepatitis B with delta-agent	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
B18.1	Chronic viral hepatitis B without delta-agent	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
B18.2	Chronic viral hepatitis C	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K70.2	Alcoholic fibrosis and sclerosis of liver	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K76.0	Fatty change of liver, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73	Chronic hepatitis, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73.0	Chronic persistent hepatitis, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73.1	Chronic lobular hepatitis, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73.2	Chronic active hepatitis, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73.8	Other chronic hepatitis, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K73.9	Chronic hepatitis, unspecified	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K75.4	Autoimmune hepatitis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
K75.8	Other specified inflammatory liver diseases	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Chronic Liver Disease	Index	Dahiya, 2021
D57.21.1	Sickle-cell/Hb-C disease with acute chest syndrome	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.20	Sickle-cell/Hb-C disease without crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.2	Sickle-cell/Hb-C disease	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.21	Sickle-cell/Hb-C disease with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.21.2	Sickle-cell/Hb-C disease with splenic sequestration	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.219	Sickle-cell/Hb-C disease with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.0	Hb-SS disease with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.00	Hb-SS disease with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.41	Sickle-cell thalassemia with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.01	Hb-SS disease with acute chest syndrome	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.02	Hb-SS disease with splenic sequestration	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.4	Sickle-cell thalassemia	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.40	Sickle-cell thalassemia without crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library

D57.411	Sickle-cell thalassemia with acute chest syndrome	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.419	Sickle-cell thalassemia with crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.1	Sickle-cell disease without crisis	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
D57.412	Sickle-cell thalassemia with splenic sequestration	ICD-10-CM	Medical Claims - Adult record	High-Risk Condition - Sickle Cell Disease	Index	Action Measure Library
B16.0	Acute hepatitis B with delta-agent with hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B16.1	Acute hepatitis B with delta-agent without hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B16.2	Acute hepatitis B without delta-agent with hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B16.9	Acute hepatitis B without delta-agent and without hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B18.0	Chronic viral hepatitis B with delta-agent	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B18.1	Chronic viral hepatitis B without delta-agent	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B19.10	Unspecified viral hepatitis B without hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B19.11	Unspecified viral hepatitis B with hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B17.10	Acute hepatitis C without hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B17.11	Acute hepatitis C with hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B18.2	Chronic viral hepatitis C	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B19.20	Unspecified viral hepatitis C without hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B19.21	Unspecified viral hepatitis C with hepatic coma	ICD-10	Medical Claims - Adult record	Active Infections - Hepatitis B and C virus	Index	Action Measure Library
B20	Human immunodeficiency virus [HIV] disease	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.711	Human immunodeficiency virus [HIV] disease complicating pregnancy, first trimester	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.713	Human immunodeficiency virus [HIV] disease complicating pregnancy, third trimester	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.72	Human immunodeficiency virus [HIV] disease complicating childbirth	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.712	Human immunodeficiency virus [HIV] disease complicating pregnancy, second trimester	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.719	Human immunodeficiency virus [HIV] disease complicating pregnancy, unspecified trimester	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
O98.73	Human immunodeficiency virus [HIV] disease complicating the puerperium	ICD-10	Medical Claims - Adult record	Active Infections - HIV	Index	Action Measure Library
D50	Iron deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D50.0	Iron deficiency anemia secondary to blood loss (chronic)	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D50.1	Sideropenic dysphagia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D50.8	Other iron deficiency anemias	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D50.9	Iron deficiency anemia, unspecified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51	Vitamin B12 deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.0	Vitamin B12 deficiency anemia due to intrinsic factor deficiency	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.1	Vitamin B12 deficiency anemia due to selective vitamin B12 malabsorption with proteinuria	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.2	Transcobalamin II deficiency	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.3	Other dietary vitamin B12 deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.8	Other vitamin B12 deficiency anemias	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D51.9	Vitamin B12 deficiency anemia, unspecified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D52	Folate deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D52.0	Dietary folate deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D52.1	Drug-induced folate deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D52.8	Other folate deficiency anemias	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D52.9	Folate deficiency anemia, unspecified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53	Other nutritional anemias	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53.0	Protein deficiency anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53.1	Other megaloblastic anemias, not elsewhere classified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53.2	Scorbutic anemia	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53.8	Other specified nutritional anemias	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D53.9	Nutritional anemia, unspecified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D63.1	Anemia in chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
D64.9	Anemia, unspecified	ICD-10	Medical Claims - Adult record	High-risk conditions - anemia	Index	Action Measure Library
B67.31	Echinococcus granulosus infection, thyroid gland	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E00.1	Congenital iodine-deficiency syndrome, myxedematous type	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E00.9	Congenital iodine-deficiency syndrome, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E01.0	Iodine-deficiency related diffuse (endemic) goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E02	Subclinical iodine-deficiency hypothyroidism	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.1	Congenital hypothyroidism without goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.2	Hypothyroidism due to medications and other exogenous substances	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.3	Postinfectious hypothyroidism	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.5	Myxedema coma	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.8	Other specified hypothyroidism	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.21	Thyrotoxicosis with toxic multinodular goiter with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.30	Thyrotoxicosis from ectopic thyroid tissue without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.31	Thyrotoxicosis from ectopic thyroid tissue with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.81	Other thyrotoxicosis with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.1	Subacute thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.2	Chronic thyroiditis with transient thyrotoxicosis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.3	Autoimmune thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E07.0	Hypersecretion of calcitonin	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E07.1	Dyshormonogenic goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E07.81	Sick-euthyroid syndrome	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E07.9	Disorder of thyroid, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
O90.5	Postpartum thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
A18.81	Tuberculosis of thyroid gland	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E00.0	Congenital iodine-deficiency syndrome, neurological type	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E00.2	Congenital iodine-deficiency syndrome, mixed type	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E01.1	Iodine-deficiency related multinodular (endemic) goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E01.2	Iodine-deficiency related (endemic) goiter, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E01.8	Other iodine-deficiency related thyroid disorders and allied conditions	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.0	Congenital hypothyroidism with diffuse goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.4	Atrophy of thyroid (acquired)	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E03.9	Hypothyroidism, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E04.0	Nontoxic diffuse goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E04.1	Nontoxic single thyroid nodule	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E04.2	Nontoxic multinodular goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E04.8	Other specified nontoxic goiter	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E04.9	Nontoxic goiter, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.10	Thyrotoxicosis with toxic single thyroid nodule without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.11	Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.20	Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.40	Thyrotoxicosis factitia without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.41	Thyrotoxicosis factitia with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.80	Other thyrotoxicosis without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E05.91	Thyrotoxicosis, unspecified with thyrotoxic crisis or storm	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.0	Acute thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.4	Drug-induced thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.5	Other chronic thyroiditis	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E06.9	Thyroiditis, unspecified	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E07.89	Other specified disorders of thyroid	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
E89.0	Postprocedural hypothyroidism	ICD-10	Medical Claims - Adult record	High risk conditions - thyroid disorders	Index	Action Measure Library
Q20	Congenital malformations of cardiac chambers and connections	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.0	Common arterial trunk	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.2	Double outlet left ventricle	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.3	Discordant ventriculoarterial connection	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.8	Other congenital malformations of cardiac chambers and connections	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.0	Ventricular septal defect	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.2	Septal defect, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.3	Tetralogy of Fallot	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.4	Aortopulmonary septal defect	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.8	Other congenital malformations of cardiac septa	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22	Congenital malformations of pulmonary and tricuspid valves	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.0	Pulmonary valve atresia	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.3	Other congenital malformations of pulmonary valve	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.4	Congenital tricuspid stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.8	Other congenital malformations of tricuspid valve	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library

Q22.9	Congenital malformation of tricuspid valve, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23	Congenital malformations of aortic and mitral valves	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.0	Congenital stenosis of aortic valve	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.1	Congenital insufficiency of aortic valve	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.3	Congenital mitral insufficiency	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.9	Congenital malformation of aortic and mitral valves, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.0	Dextrocardia	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.1	Levocardia	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.3	Pulmonary infundibular stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.5	Malformation of coronary vessels	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25	Congenital malformations of great arteries	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.2	Atresia of aorta	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.21	Interruption of aortic arch	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.42	Hypoplasia of aorta	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.43	Congenital aneurysm of aorta	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.45	Double aortic arch	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.46	Tortuous aortic arch	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.47	Right aortic arch	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.48	Anomalous origin of subclavian artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.5	Atresia of pulmonary artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.7	Other congenital malformations of pulmonary artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.72	Congenital pulmonary arteriovenous malformation	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.8	Other congenital malformations of other great arteries	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.9	Congenital malformation of great arteries, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.1	Persistent left superior vena cava	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.5	Anomalous portal venous connection	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.8	Other congenital malformations of great veins	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.9	Congenital malformation of great vein, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.1	Double outlet right ventricle	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.4	Double inlet ventricle	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.5	Discordant atrioventricular connection	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q20.6	Isomerism of atrial appendages	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21	Congenital malformations of cardiac septa	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.1	Atrial septal defect	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q21.9	Congenital malformation of cardiac septum, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.1	Congenital pulmonary valve stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.2	Congenital pulmonary valve insufficiency	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.5	Ebstein's anomaly	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q22.6	Hypoplastic right heart syndrome	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.2	Congenital mitral stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.4	Hypoplastic left heart syndrome	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q23.8	Other congenital malformations of aortic and mitral valves	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24	Other congenital malformations of heart	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.2	Cor triatriatum	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.4	Congenital subaortic stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.6	Congenital heart block	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.8	Other specified congenital malformations of heart	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q24.9	Congenital malformation of heart, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.0	Patent ductus arteriosus	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.1	Coarctation of aorta	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.3x	Supravalvular aortic stenosis	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.4x	Other congenital malformations of aorta	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.6x	Stenosis of pulmonary artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.71	Coarctation of pulmonary artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q25.79	Other congenital malformations of pulmonary artery	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26	Congenital malformations of great veins	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.0	Congenital stenosis of vena cava	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.2	Total anomalous pulmonary venous connection	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.3	Partial anomalous pulmonary venous connection	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.4	Anomalous pulmonary venous connection, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
Q26.6	Portal vein-hepatic artery fistula	ICD-10	Medical Claims - Adult record	High-risk condition - congenital heart disease	Index	Action Measure Library
I26.09	Other pulmonary embolism with acute cor pulmonale	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
I27.81	Cor pulmonale (chronic)	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
I27.89	Other specified pulmonary heart diseases	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
I27.9	Pulmonary heart disease, unspecified	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J40	Bronchitis, not specified as acute or chronic	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J41.0	Simple chronic bronchitis	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J41.1	Mucopurulent chronic bronchitis	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J41.8	Mixed simple and mucopurulent chronic bronchitis	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J42	Unspecified chronic bronchitis	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J43.9	Emphysema, unspecified	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J44.1	Chronic obstructive pulmonary disease with [acute] exacerbation	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J44.9	Chronic obstructive pulmonary disease, unspecified	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.20	Mild intermittent asthma, uncomplicated	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.21	Mild intermittent asthma with [acute] exacerbation	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.22	Mild intermittent asthma with status asthmaticus	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.901	Unspecified asthma with [acute] exacerbation	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.902	Unspecified asthma with status asthmaticus	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.909	Unspecified asthma, uncomplicated	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.990	Exercise induced bronchospasm	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.991	Cough variant asthma	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J45.998	Other asthma	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J47.1	Bronchiectasis with [acute] exacerbation	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
J47.9	Bronchiectasis, uncomplicated	ICD-10	Medical Claims - Adult record	gh-risk condition - Chronic Obstructive Pulmonary Dise	Index	Action Measure Library
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 thr	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chr	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chr	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.1	Chronic kidney disease, stage 1	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.2	Chronic kidney disease, stage 2 (mild)	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.3	Chronic kidney disease, stage 3 (moderate)	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.31	Chronic kidney disease, stage 3a	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
R88.0	Cloudy (hemodialysis) (peritoneal) dialysis effluent	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
Z49.32	Encounter for adequacy testing for peritoneal dialysis	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
D63.1	Anemia in chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
E09.22	Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney dise	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.30	Chronic kidney disease, stage 3 unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.32	Chronic kidney disease, stage 3b	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.4	Chronic kidney disease, stage 4 (severe)	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.5	Chronic kidney disease, stage 5	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.6	End stage renal disease	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
N18.9	Chronic kidney disease, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
Z49.31	Encounter for adequacy testing for hemodialysis	ICD-10	Medical Claims - Adult record	High-risk condition - Chronic Kidney disease	Index	Action Measure Library
Q90.0	Trisomy 21, nonmosaic (meiotic nondisjunction)	ICD-10	Medical Claims - Adult record	High-risk condition - Down's syndrome	Index	Marlow, 2021
Q90.1	Trisomy 21, mosaicism (mitotic nondisjunction)	ICD-10	Medical Claims - Adult record	High-risk condition - Down's syndrome	Index	Marlow, 2021
Q90.2	Trisomy 21, translocation	ICD-10	Medical Claims - Adult record	High-risk condition - Down's syndrome	Index	Marlow, 2021
Q90.9	Down syndrome, unspecified	ICD-10	Medical Claims - Adult record	High-risk condition - Down's syndrome	Index	Marlow, 2021
A69.20	Lyme disease, unspecified	ICD-10	Medical Claims - Adult record	Active infections - Lyme Disease	Index	Schubert, 2020
A69.29	Other conditions associated with Lyme disease	ICD-10	Medical Claims - Adult record	Active infections - Lyme Disease	Index	Schubert, 2020
F00-99	Any registered psychiatric diagnosis	ICD-10	Medical Claims - Adult record	High-risk conditions - Mental Health Conditions	Index	Heuckendorf, 2022

A02x	Antacids and medications for peptic ulcer	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
A03x	Medications for functional gastrointestinal disorders	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
A07x	Antidiarrheals, intestinal anti-inflammatory/anti-infective agents	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
A08x	Antibesity preparations, excluding diet products	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
A10x	Medications for diabetes	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
B01x	Antithrombotic agents	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
C05x	Vasoprotectives	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
C07x	β-adrenoceptor blockers	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
C09x	Agents acting on the renin-angiotensin system	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
D01x	Antifungals for dermatological use	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
D06x	Antibiotics and chelating agents for dermatological use	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
D07x	Dermal corticosteroids	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
D10x	Anti-acne preparations	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
G01x	Gynaecological anti-infectives	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
G02x	Other gynaecologicals	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
G03x	Sex hormones	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
H01Bx	Posterior pituitary lobe hormones	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
H03x	Thyroid therapy	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01x	Antibacterials for systemic use	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01Ax	Tetracyclines	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01Cx	β-lactam antibacterials, penicillins	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01Dx	Sulphonamides and trimethoprim	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01F _x	Macrolides, lincosamides and streptosamins	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
J01X _x	Other antibacterials	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
L _x	Antineoplastic and immunomodulating agents	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
M01A	Anti-inflammatory and antirheumatic products, non-steroids	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
M03x	Muscle relaxants	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
N02 Ax	Opioids	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
N03x	Anti-epileptics	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
N05 Ax	Antipsychotics	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
N05Cx	Anxiolytics, hypnotics and sedatives	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
N06Ax	Antidepressants	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
P01x	Antiprotozoals	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
R01x	Nasal preparations	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
R03x	Anti-asthmatics	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
R05x	Cough and cold preparations	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
R06x	Antihistamines	ATC	Pharmacy Claims	Known teratogenic Medications	First trimester	Lutein et al. 2016
G02CC02	Naproxen	ATC	Medical Claims - Adult record	Known Teratogenic medications	Baseline period	Lutein, 2016
C07AA02	Oxprenolol	ATC	Medical Claims - Adult record	Known Teratogenic medications	Baseline period	Lutein, 2016
N03AB02	Phenytoin	ATC	Medical Claims - Adult record	Known Teratogenic medications	Baseline period	Lutein, 2016
G03DA04	Progesterone	ATC	Medical Claims - Adult record	Known Teratogenic medications	Baseline period	Lutein, 2016
N03AG01	Valproic acid	ATC	Medical Claims - Adult record	Known Teratogenic medications	Baseline period	Lutein, 2016
A56	Other sexually transmitted chlamydial diseases	ICD-10-CM	Medical Claims - Adult record	Past infections	Index	WHO Int 2019
B58.9	Toxoplasmosis, unspecified	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
A53.9	Syphilis, unspecified	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B06.x	Rubella [German measles]	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
O98.5	Other viral diseases complicating pregnancy, childbirth and the puerperium	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
O35.3	Maternal care for (suspected) damage to fetus from viral disease in Adult	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B25.x	Cytomegaloviral disease	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B00.x	Herpesviral [herpes simplex] infections	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
A60	Anogenital herpesviral [herpes simplex] infection	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B16	Acute hepatitis B	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B17	Other acute viral hepatitis	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B17.0	Acute delta-(super)infection in chronic hepatitis B	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B17.1	Acute hepatitis C	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B20.x	Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic dis	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B21.x	Human immunodeficiency virus [HIV] disease resulting in malignant neoplasms	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B22.x	Human immunodeficiency virus [HIV] disease resulting in other specified diseases	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B23.x	Human immunodeficiency virus [HIV] disease resulting in other conditions	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B24.x	Unspecified human immunodeficiency virus [HIV] disease	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B34.3	Parvovirus infection, unspecified site	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
A59.x	Trichomoniasis	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
Z22.4	Carrier of infections with a predominantly sexual mode of transmission	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
Z20.2	Contact with and exposure to infections with a predominantly sexual mode of trans	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
Z22.4	Carrier of infections with a predominantly sexual mode of transmission	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
A54.9	Gonococcal infection, unspecified	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
O98.2	Gonorrhoea complicating pregnancy, childbirth and the puerperium	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B54.x	Unspecified malaria	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B50.x	Plasmodium falciparum malaria	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B52.x	Plasmodium malariae malaria	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B53	Other parasitologically confirmed malaria	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B97.7	Papillomavirus as the cause of diseases classified to other chapters	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
A69.2	Lyme disease	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
J15.3	Pneumonia due to streptococcus, group B	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B95.1	Streptococcus, group B, as the cause of diseases classified to other chapters	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B97.1	Enterovirus as the cause of diseases classified to other chapters	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B34.1	Enterovirus infection, unspecified site	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019
B01	Varicella [chickenpox]	ICD-10-CM	Medical Claims - Adult record	Active Infections	Index	WHO Int 2019

*for other SARS-CoV-2 monoclonal antibody treatments, please see the immunomodulating medication tab

Code	Descriptor	Type	Encounter Type	Measure	Ascertainment Period	Source
* For congenital infections pertaining to the offspring covariates that are only found on the infant record are included here. For the complete list, please see the Pregnancy Covariates tab						
G40.X	Epilepsy and recurrent seizures	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
R56.X	Convulsions, not elsewhere classified	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.0X	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.1X	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.2X	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.3X	Generalized idiopathic epilepsy and epileptic syndromes	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.4X	Other generalized epilepsy and epileptic syndromes	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.AX	Absence epileptic syndrome	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.BX	Juvenile myoclonic epilepsy [impulsive petit mal]	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.81X	Lennox-Gastaut syndrome intractable	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
G40.82X	Epileptic spasms intractable	ICD-10-CM	Medical Claims - Adult record	Comorbidities - Epilepsy	Index	Smith, 2020
P00.2	Fetus and newborn affected by maternal infectious and parasitic diseases	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P35.2	Congenital herpesviral [herpes simplex] infection	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P35.1	Congenital cytomegalovirus infection	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P00.2	Fetus and newborn affected by maternal infectious and parasitic diseases	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P00.2	Fetus and newborn affected by maternal infectious and parasitic diseases	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P37.3	Congenital falciparum malaria	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P23.3	Congenital pneumonia due to streptococcus, group B	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
P36.0	Sepsis of newborn due to streptococcus, group B	ICD-10-CM	Medical Claims - Infant record	Confenital Infections	Index	WHO Int 2019
U07.1	COVID-19	ICD-10-CM	Medical Claims - Infant record	SARS-CoV-2 Infection	Index	WHO, 2022

Annex 2: Data Feasibility and Assessment

Fit-For-Purpose Feasibility Assessment Overview

To assess the candidate data sources for O-STEREO PASS, a fit-for-purpose feasibility assessment following the structured fit-for-purpose (SPIFD¹) process was conducted.

To address the suitability of each dataset in the context of the O-STEREO objectives (Section 8.2 in the protocol) three key aspects were evaluated:

1. Data reliability
2. Data relevance
3. Data accessibility

The data reliability assessment focused on the trustworthiness and credibility of the data. To assess data reliability, the existing quality control and assurance processes were evaluated. The data relevance was evaluated by first outlining the minimum data criteria (Table 1) for the study based on the research question and study objectives. The criteria needed was operationalized to data needs to conduct the feasibility assessment across each data source. Findings were then used to rank each of the data sources by criteria from 0 (does not meet study requirements) to 5 (many/nearly all data requirements met). Data accessibility was assessed based on barriers to interaction with, or use of the data for study purposes.

Noteworthy, the recommendations and rankings from the current feasibility assessment are based on known information as of July and August 2022. Considering the rapidly evolving clinical and epidemiological landscape of COVID-19 and access of EVUSHELD in each country, the recommendations and rankings from this feasibility assessment may not be reflective of the future state of EVUSHELD or COVID-19.

Identification of Feasibility Candidate Data Sources

To identify existing healthcare data sources in the FFP assessment, a landscape study was conducted across countries in the European Medical Agency Jurisdiction, herein referred to as “European” and selected non-European countries with known or expected access to EVUSHELD in 2022 (Table 2). Potential data sources were identified through an in-depth literature search of published peer-reviewed articles and conference abstracts, searching the grey literature, relevant

¹ Gatto, NM et al. (2022). The Structured Process to Identify Fit-For-Purpose Data: A Data Feasibility Assessment Framework. Clin. Pharmacol. Ther., 111(1), 122-134. <https://doi.org/10.1002/cpt.2466>

publicly available inventories (Birthcohorts.net²; EnCEPP Resource Database³ and PAS Register; IMIConception⁴), and data sources known to the researchers.

Within each geography a list of data sources (Table 3) were selected for a first round of feasibility to select candidate data sources for the in-depth FFP assessment. The first round of feasibility included information gathering of data relevance and outreach to inform the willingness to participate in O-STEREO. The information gathered included data availability related to EVUSHELD exposures administered in secondary care during pregnancy and follow-up of eligible offsprings to at least one-year of life, data recency, and overall size in terms of annual pregnancies or births per year. Data sources were then excluded based on a lack of willingness to participate in O-STEREO or lack of relevant data (Figure 1). Only an explicit decline to participate qualified a data source for exclusion and any data source with a lack of response was still considered for assessment. Across the candidate data sources, the data sources selected met the minimum requirements (Table 1) for the study population, outcomes, covariates and exposures. The findings related to data relevance and data accessibility are summarized in Figure 2 and details on the data source characteristics are listed in Table 4 and Table 5. Additional rationale for the selection of these data sources is provided below.

In the context of European data sources, limited relevant existing healthcare data sources were identified in the landscape and aligned with existing catalogs and previous landscapes^{4,5}. No existing data sources were identified in Austria or Belgium and were not considered for the first round of feasibility. Potential data sources in France, Germany, Italy, and Spain were further assessed in the first round of feasibility. After this initial feasibility, only French data sources were further considered for the FFP assessment (Figure 1). The GePard database (Germany) was selected for further assessment, but excluded based on lack of capture of EVUSHELD exposure. At the time of feasibility, EVUSHELD was available within the framework of the Supply Assurance for Medical Needs Ordinance and only exposures reimbursed under statutory insurances were captured in GePard⁶. Multiple regionally linked Italian databases were considered for the initial feasibility. One explicitly declined to participate and upon further investigation it was confirmed that capture of data related to EVUSHELD exposure was lacking in the additional two data sources. Within Spain, the Valencia Integrated Database (VID) was identified for further

² Search. Birthcohorts.net. Available at: <https://www.birthcohorts.net/birthcohorts/search/> (Accessed : September 7, 2022).

³ ENCePP Resources Database. Available at <https://www.encepp.eu/encepp/resourcesDatabase.jsp> (Accessed : September 7, 2022)

⁴ Loane, Maria, Given, Joanne, & Coste, Florence. (2020). Spreadsheet containing all additional data sources for the ConcePTION Data Source Catalogue (D1.1). <https://doi.org/10.5281/zenodo.5824739>

⁵ Charlton RA, et al. Healthcare databases in Europe for studying medicine use and safety during pregnancy. *pharmacoepidemiology and drug safety*. 2014 Jun;23(6):586-94. <https://doi.org/10.1002/pds.3613>

⁶ Authorisation Granted for the Monoclonal Antibody Combination Evusheld (Tixagevimab and Cilgavimab) for COVID-19 Prevention. Available at: <https://www.pei.de/EN/newsroom/hp-news/2022/220325-authorisation-monoclonal-antibody-evusheld.html> (Accessed: September 19, 2022)

investigation, however based on the expected low sample size across the planned study period combined with an explicit decline to participate, it was not further considered. During the feasibility assessment, 0 EVUSHELD exposures during pregnancy were observed across the largest contributing hospitals in the VID.

In non-European countries, three data sources in the USA and one data source in Canada were selected for the first round of feasibility. Data sources in other non-European countries (Australia, Israel, United Arab Emirates, Singapore) were not considered due to a lack of relevant data or unwillingness to participate. After FFP assessment, the HealthVerity Maternal Outcomes Masterset (HV MOM) in the USA and the Canadian Mother Child Cohort (CaMCCo) in Canada were selected. The two other US databases included for FFP assessment were excluded due to low sample size and lack of relevant data.

Fit-For-Purpose Assessment Findings

Système National des Données de Santé (SNDS) in France is FFP based on the known reliability of pregnancy episodes and birth ascertainment in safety studies. Furthermore, SNDS is a nationally representative data source capturing relevant data on treatments administered in secondary care and all prescriptions in addition to the obstetric, neonatal, and infant outcomes. SNDS reported 82 dispensed units of EVUSHELD in 2021 and 8 932 from January to April 2022 in the total database population.

In the US, the HV MOM data source is considered FFP and will have significantly more patients and data in the upcoming years. Outcome ascertainment in MOM based on validated algorithms and the ability to link additional data types (COVID-19 labs and Hospital Chargemaster Data) increases the data relevance for study design elements related to COVID-19. The biggest strengths related to the MOM dataset include the capture of Medicaid patients and the limited data lag. From March 2022 until July 2022, HV MOM recorded 72 exposures to EVUSHELD in the complete database. Insights related to descriptive outcomes through the first year of EVUSHELD availability will be available by the end of 2023.

To further supplement, we recommend deriving a Canadian cohort from the CaMCCo. CaMCCo currently captures all pregnancies and exposures across 9 provinces in Canada. Whilst the data provinces vary within each province, the data relevance related to O-STEREO is high with capture of all key outcomes, covariates, and exposure data needed in 8 of the 9 provinces. It is expected that both the US and Canadian cohorts are generalizable to a European EVUSHELD eligible population. At the time of this report, the EVUSHELD guidance from FDA and HealthCanada reflected that of EMA. We recommend that generalizability of both the US and Canadian cohorts be assessed as part of the O-STEREO study per EMA GVP guidance.

Each of the above selected data sources are established data sources with quality control and assurance checks of the validity, plausibility, consistency, conformance, and completeness.

Table 1. Minimum data criteria

Design Element	Operational Definition	Minimal criteria for valid capture
Source Population	Pregnancy episode	- Ability to capture a pregnancy episode - Last menstrual period - Pregnancy diagnosis - Diagnosis and/or procedures to identify pregnancy outcomes
Demographics	- Age between 18 and 49 - Female sex - Race/Ethnicity - Geography - Health Plan	- Mother Birthdate - Sex - SES Factors - Country/region
Pregnancy characteristics	- Gestational age - Care setting at delivery - C-section delivery	- Ability to determine gestational age: Diagnosis code and Procedure codes to identify pregnancy outcomes - Encounter for inpatient or outpatient setting - Inpatient procedures codes
Pregnancy history	- Prior pregnancy history - Maternal parity - Pre-pregnancy BMI	- Inpatient or outpatient diagnosis - Vitals (height, weight), date and unit of measure
Comorbidities	- High risk conditions - Other comorbidities - Past infection - Active infection - SARS-CoV-2 infection	- Inpatient or outpatient diagnosis - Pregnancy serology tests - Covid-19 lab test
Co-medications and substance abuse	- Known teratogenic medications - Substance use (tobacco, alcohol, illicit drugs) - Other SARS-CoV-2 monoclonal antibody - Other COVID-19 therapies	- Inpatient or outpatient prescription (Treatment name, dosing, prescription date, administration date) - Inpatient or outpatient diagnosis - Covid-19 laboratory test (name, date and result) - Inpatient or outpatient encounter for COVID-19 immunization

Design Element	Operational Definition	Minimal criteria for valid capture
	COVID-19 vaccination status	
Pregnancy outcomes	- Spontaneous abortion - Preterm live birth - Preeclampsia - Ectopic Pregnancy - Maternal Death - Stillbirth - Gestational diabetes - Gestational hypertension - Live Birth	- Diagnosis code - Inpatient procedures (codes and results) - Gestational age - Mortality (date of death) - Laboratory tests (name, date, unit and results)
Neonatal outcomes	- Neonatal death - Respiratory Distress Syndrome in the Newborn - Small for Gestational Age (SGA) - Low Birth Weight (LBW)	- Diagnosis code - Gestational Age - Mortality (Date of death) - Weight at birth (unit, date)
Infant outcomes	- Infant death - Failure to thrive - Major Congenital Malformations	- Diagnosis code - Baby Birthdate - Mortality (Date of death and cause) - Weight at birth (unit, date)
EVUSHELD Exposure	EVUSHELD treatment	- Outpatient prescriptions - Inpatient and outpatient medication administrations - Start date of treatment - Treatment duration - Route of administration - Dosage

Design Element	Operational Definition	Minimal criteria for valid capture
Offspring covariates	• Sex • Breastfed • Congenital infections • SARS-CoV-2 Infection	• Child birthdate • Encounter for sex (EMR or claims) • Encounter for breastfeeding (EMR) • Inpatient or outpatient diagnosis • Covid-19 laboratory test

Table 2. Summary of Geographies with known or expected access to EVUSHLED 2022 (as of August 2022)

Geographic Group	Countries in Scope for O-STEREO Feasibility
European ¹	Austria, Belgium, Germany, France, Spain
Non-European	Australia, Canada, Singapore, United Arab Emirates, United States

¹Defined as countries in the European Medical Agency jurisdiction included those in the European Union and selected countries in the European Economic Area (Iceland, Norway, and Liechtenstein).

Table 3: Summary of Data Source Identified for Feasibility

Country	Data source identified
USA	MOM (HealthVerity), Premier PINC AI™ Maternal Health database, KPNC/KPSC
Canada	CaMCCo, BORN registry
Australia	WA Midwives notification system, VPDC, NSW PDC, QPDC (PHRN)
UK	CPRD, SAIL (Wales), COPS (Scotland), OpenSafely
France	SNDS, AP-HP
Italy	Healthcare utilization databases of Lombardy, Region Emilia Romagna (RER) Database
Germany	GePard
Spain	Valencia Health System Integrated database (VID)
UAE	Dubai real world claims database, United Arab Emirates Birth Cohort Study (UAE-BCS)
Israel	Clalit Data Warehouse, MDClone (Maccabi, Leumit & Meuhedet HMOs)
Singapore	GUSTO cohort, KK Women's and Children's Hospital (KKH)

Table 4: Database characteristics of proposed datasets

Database	CaMCCO	MOM	SNDS
Country	Canada	US	France
Database holder	Canadian Provincial Health Authorities	HealthVerity	French Health Authorities
Proposed Research Partner	CHU Justine	HealthVerity	Bordeaux University (BPE)
Healthcare setting	Provincial healthcare administrative databases	All settings	French National Health Insurance system
Type of Data	Medical and pharmacy claims, hospital stay data, birth records and sociodemographic data	Medical and pharmacy claims, labs, EMR and hospital data master in Q4 2022, mortality records.	Outpatient medical and pharmacy claims, hospital discharge summaries, death and medical causes of death
Existing mother-baby link	Yes	Yes	Yes
Estimated number of pregnancies per year	4 million pregnancies over 25 years	~1 250 000	Unknown
Estimated number of births per year	Unknown	390 000 linked babies	738 000

Database	CaMCCO	MOM	SNDS
Start of data collection	1995	2017	2007
Data Lag	1 year	4 months	1 year
Data Access Timelines	1 year	1 month	1-1.5 years
Access to individual patient-level data and ability to connect to AEP	No	Yes	No

Table 5: Data source characteristics

Country	Data source characteristics
USA - HealthVerity: Maternal Outcomes Masterset	The HealthVerity Maternal Outcomes Masterset (HV MOM) database is a de-identified healthcare aggregated database of over 150 million pregnant women and newborns including, closed medical and pharmacy claims from over 150 payers (commercial and Medicaid), lab, EMR, hospital chargemaster, and mortality data. The dataset is refreshed every 4 months and covers encounters from January 1, 2014 up to 4 months from the date of data extraction. Linkages between the mother and baby are established through a de-identified crosswalk that leverages the mother's age, birth event claims, subscriber and group ID, diagnosis, and procedure codes. All longitudinal treatment data on dispensed prescriptions, inpatient and outpatient diagnosis, treatment, and procedures are ascertained through code-based algorithms combining Healthcare Common Procedure Coding System (HCPCS), ICD, and NDC codes via evidence from administrative claims. Related obstetric, birth, and offspring outcomes are ascertained through code-based algorithms using P- and Z-ICD codes. Subject-level date of death (month and year) is derived from an external source (Private Source 90) that combines over 40,000 sources with a 3-month lag. Key confounders such as age, sex, race/ethnicity, and payer are available for every mother. Mothers and babies are continuously followed-up through the end of the mother's enrolment on an insurance plan.
Canada - Canadian Mother Child Cohort	The Canadian Mother Child Cohort (CaMCCo) is a population-based cohort capturing all pregnancies and births across six provinces in Canada (Alberta, British Columbia, Ontario, Québec, Manitoba, and Saskatchewan). 3 other provinces will join the cohort soon. Data is aggregated at a provincial level using a patient unique encrypted identifier to link multiple administrative and hospital databases with registries (pregnancy, birth, and death) within each region. The cohort is annually refreshed with a one-year data lag resulting in coverage from 1995 up to one year prior to the date of data extraction. Data related to diagnosis, procedures, medication use, sociodemographic indications, and hospital stay are all available. Data on dates of pregnancy and births, first names, and family names are used to facilitate the link between mothers and babies by each provincial data custodian. All related obstetric, birth, and offspring outcomes are captured through code bases algorithms. Data related to breastfeeding is not currently captured. Centre Hospitalier Universitaire Sainte-Justine will be the data access provider for CaMCCo for this study.

Country	Data source characteristics
France - Système National des Données de Santé	The Système National des Données de Santé (SNDS), the French National Health Insurance database, is a national healthcare aggregated database covering approximately 97% of the French population from birth or immigration through death or emigration. Data is available from 2006 up to a one-year lag from date of data extraction with annual refreshes. Leveraging a unique pseudonymized identifier, the SNDS links all reimbursed outpatient claims across healthcare insurance schemes from the Datamart de Consommation Inter-Regimes (DCIR) database with hospital discharge summaries from the Programme de Médicalisation des Systèmes d'Information (PMSI) database, and mortality data from the national death registry. Individual pregnancy episodes are identified through a validated code-based algorithm based on discharge diagnosis and medical procedures. Linkages to subsequent births are made through a unique identifier to any birth event (live or non-live) occurring after 22 weeks of gestation. All reimbursed medication exposures are captured across all settings. Drugs are classified with the ATC classification and outpatient medical procedures are coded according to the Classification Commune des Actes Médicaux (CCAM). Evidence of medical history or active comorbidities of a related diagnosis is derived from an ICD-10 based algorithm. Only COVID-19 diagnoses that lead to hospitalisation are currently captured in SNDS through evidence of diagnosis from a hospital discharge; subject-level linking to national databases for COVID-19 vaccination (système d'information Vaccin Covid, VAC-SI) and testing (Système d'Informations de dépistage populationnel, SI-DEP) can be conducted for complete ascertainment of COVID-19 vaccination and diagnosis status. Covariates such as birth year, gender, and area of residence are all available for each mother. Bordeaux PharmacoEpi (BPE), affiliated with the University of Bordeaux, will be the Data Access Provider for SNDS for this study.

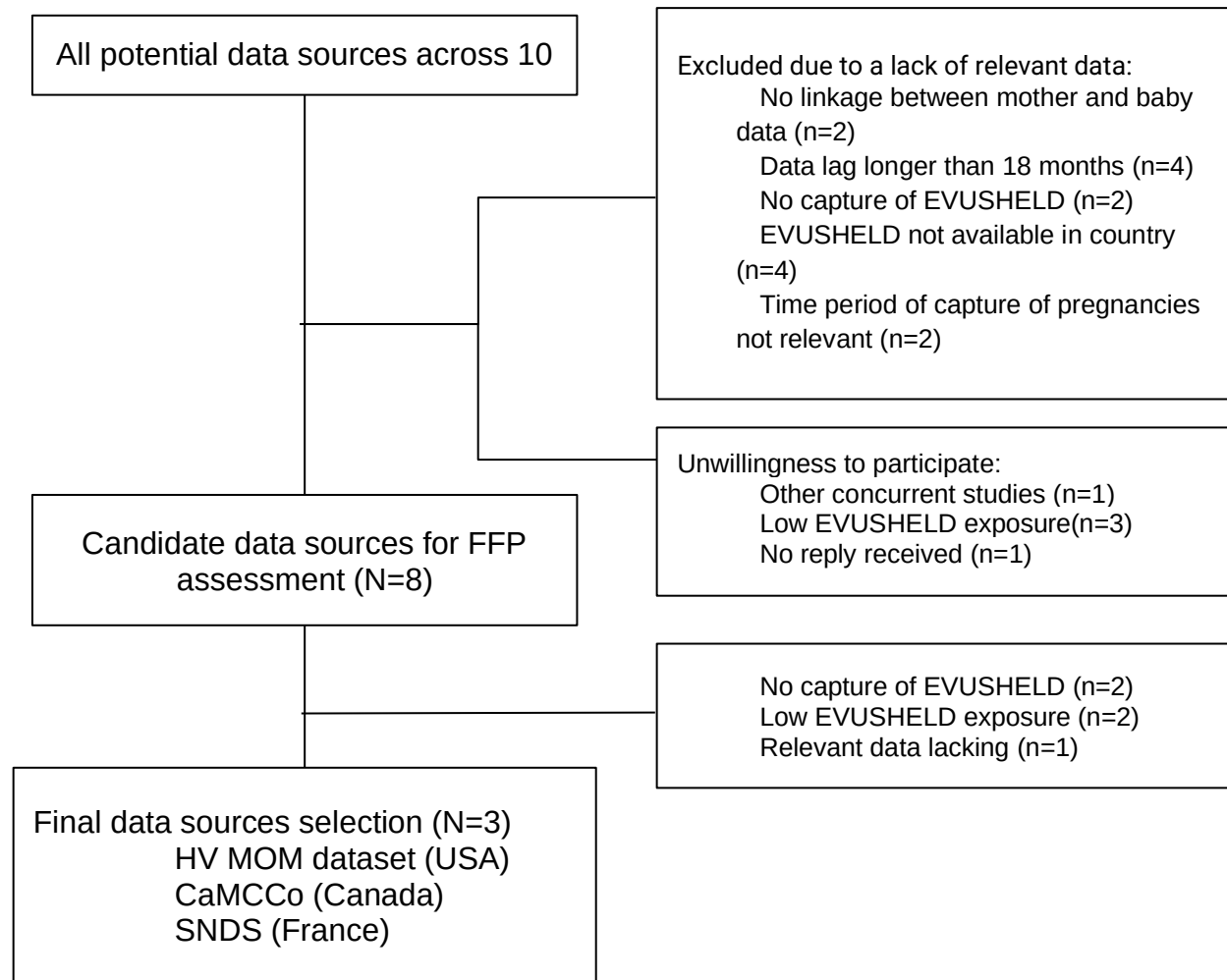


Figure 1: Attrition of Candidate Data Sources for Feasibility

Study Design Element		HV MOM	CaMCCo	SNDS
Study Population	Study eligible sample size	5	3	4
	Study population (I/E)	4	5	5
Outcomes	Obstetric outcomes	4	5	4
	Neonatal outcomes	5	5	4
	Infant outcomes	4	5	5
Maternal and offspring Covariates	Demographics	4	4	4
	Pregnancy characteristics	4	5	4
	Pregnancy history	3	5	4
	Comorbidities	5	4	5
	Laboratory tests	5	2	1
	Co-mediations and substance abuse	4	5	5
	Covid-19 infection and/or vaccination	5	2	5
	Offspring covariates	4	4	4
Treatments	EVUSHELD	5	3	5
	Covid-19 monoclonal antibodies	5	2	5
Data source characteristics	Data lag	5	3	3
	Accessibility	5	4	3
	Transparency	4	5	4

Figure 2: Fit-For-Purpose Heatmap (selected data sources)

LEGEND

	5 = Many/nearly all data requirements met
	4 = Several data requirements met
	3 = Likely that several data requirements are met but requires further investigation
	2 = Some data requirements met or unable to assess at this time
	1 = Data requirements not met

Annex 3: EVUSHELD dosing recommendations by country

The below table provides EVUSHELD dosing recommendations in Canada, France and the US as of 15 September 2022. Indications and dosing recommendations are subject to evolve during the conduct of the study along with future COVID-19 pandemic dynamics.

Country	Dosing recommendations
Canada	The recommended dose is 300 mg of EVUSHELD, administered as two separate 1.5 mL, sequential, injections of 150 mg of tixagevimab and 150 mg of cilgavimab. Consideration for an increase in dosage to 600 mg in regions where Omicron subvariants BA.1 and BA.1.1 are circulating, as it is unknown whether the 300 mg dose is protective of these subvariants clinically (1).
France	Early Access Authorisation: The recommended dosage is 300 mg, given as two injections: 150 mg of tixagevimab and 150 mg of cilgavimab. A higher dose of 600 mg (300 mg of tixagevimab and 300 mg of cilgavimab) or a closer re-administration may be used for prevention of Omicron subvariants (2). EU Marketing Authorisation: The recommended dose in adults and adolescents aged 12 years and older weighing at least 40 kg is 150 mg of tixagevimab and 150 mg of cilgavimab, administered as two separate sequential intramuscular injections (3).
US	The initial dosage authorised was 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections. On 29 June, 2022, Food and Drug Administration (FDA) recommended repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. Patients who have already received the previously authorised dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels to those expected for patients receiving the higher dose (4).

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