

## Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the

[Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data](#) guidance document provided by the FDA.

## Overview

<b>Title</b>	Caesarean Section Algorithm Defined in "Risk of Adverse Maternal Health Outcomes Among Pregnant Patients With and Without COVID-19: A Propensity Score Matched Analysis"
<b>Request ID</b>	cder_mpl2p_wp048
<b>Description</b>	<p>This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) codes and algorithms used to define caesarean section in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposure(s) of interest in the analysis, refer to the analysis webpage here: <a href="https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/risk-adverse-maternal-health-outcomes-among-pregnant">https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/risk-adverse-maternal-health-outcomes-among-pregnant</a></p>
<b>Outcome</b>	Caesarean section
<b>Algorithm to Define Outcome</b>	The caesarean section outcome is defined as one ICD-10-CM diagnosis code or CPT-4 procedure code for caesarean section (Code List 1) in the +/- 7 days relative to live birth delivery date.
<b>Query Period</b>	January 1, 2020 - November 30, 2023
<b>Request Send Date</b>	February 8, 2024

## Glossary

**Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or missing (U)

**Outcome** - outcome of interest (either primary or secondary)

**Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

**Query Period** - period in which the modular program looks for exposures and outcomes of interest

**Request Send Date** - date the request was sent to Sentinel Data Partners

**Code List 1. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define Cesarean Section in this Request**

Code	Description	Code	
		Category	Code Type
<b>Caesarean section</b>			
O82	Encounter for cesarean delivery without indication	Diagnosis	ICD-10-CM
Z38.01	Single liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
Z38.31	Twin liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
Z38.62	Triplet liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
Z38.64	Quadruplet liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
Z38.66	Quintuplet liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
Z38.69	Other multiple liveborn infant, delivered by cesarean	Diagnosis	ICD-10-CM
59500	Cesarean Section, Low Cervical, Including In-hospital	Procedure	CPT-4
59501	Cesarean Section, Low Cervical, Including In-hospital	Procedure	CPT-4
59514	Cesarean delivery only;	Procedure	CPT-4
59515	Cesarean delivery only; including postpartum care	Procedure	CPT-4
59520	Cesarean Section, Classic, Including In-hospital	Procedure	CPT-4
59521	Cesarean Section, Classic, Including In-hospital	Procedure	CPT-4
59540	Cesarean Section, Extraperitoneal, Including In-hospital	Procedure	CPT-4
59541	Cesarean Section, Extraperitoneal, Including In-hospital	Procedure	CPT-4
59560	Cesarean Section With Hysterectomy, Subtotal, Including	Procedure	CPT-4
59561	Cesarean Section With Hysterectomy, Subtotal, Including	Procedure	CPT-4
59580	Cesarean Section With Hysterectomy, Total, Including	Procedure	CPT-4
59581	Cesarean Section With Hysterectomy, Total, Including	Procedure	CPT-4
59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;	Procedure	CPT-4
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	Procedure	CPT-4