

## 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>	Gestational Diabetes Mellitus 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) codes and algorithms used to define gestational diabetes mellitus 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>	Gestational diabetes mellitus
<b>Algorithm to Define Outcome</b>	The gestational diabetes mellitus outcome is defined as one ICD-10-CM diagnosis code for gestational diabetes mellitus (Code List 1) from 22 weeks 0/7 days (154 days from estimated pregnancy start date) 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) Codes Used to Define Gestational Diabetes Mellitus in this Request**

Code	Description	Code	
		Category	Code Type
<b>Gestational diabetes mellitus</b>			
O24.4	Gestational diabetes mellitus	Diagnosis	ICD-10-CM
O24.41	Gestational diabetes mellitus in pregnancy	Diagnosis	ICD-10-CM
O24.410	Gestational diabetes mellitus in pregnancy, diet controlled	Diagnosis	ICD-10-CM
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled	Diagnosis	ICD-10-CM
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs	Diagnosis	ICD-10-CM
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control	Diagnosis	ICD-10-CM
O24.42	Gestational diabetes mellitus in childbirth	Diagnosis	ICD-10-CM
O24.420	Gestational diabetes mellitus in childbirth, diet controlled	Diagnosis	ICD-10-CM
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled	Diagnosis	ICD-10-CM
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs	Diagnosis	ICD-10-CM
O24.429	Gestational diabetes mellitus in childbirth, unspecified control	Diagnosis	ICD-10-CM
O24.43	Gestational diabetes mellitus in the puerperium	Diagnosis	ICD-10-CM
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled	Diagnosis	ICD-10-CM
O24.434	Gestational diabetes mellitus in the puerperium, insulin controlled	Diagnosis	ICD-10-CM
O24.435	Gestational diabetes mellitus in the puerperium, controlled by oral hypoglycemic drugs	Diagnosis	ICD-10-CM
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control	Diagnosis	ICD-10-CM