

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

Title	Small for Gestational Age Algorithm Defined in "Risk of Adverse Neonatal Health Outcomes Among Pregnant Patients With and Without COVID-19: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp041
Description	<p>This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define small for gestational age 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: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/risk-adverse-neonatal-health-outcomes-among-pregnant</p>
Outcome	Small for gestational age
Algorithm to Define Outcome	The small for gestational age outcome is defined as one International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code for small for gestational age observed in the 7 days after live birth delivery in the mother or infant claims.
Query Period	January 1, 2020 - December 31, 2022
Request Send Date	June 30, 2023

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 Small for Gestational Age in this Request

Code	Description	Code Category	Code Type
Small for gestational age			
P051	Newborn small for gestational age	Diagnosis	ICD-10-CM
P0510	Newborn small for gestational age, unspecified weight	Diagnosis	ICD-10-CM
P0511	Newborn small for gestational age, less than 500 grams	Diagnosis	ICD-10-CM
P0512	Newborn small for gestational age, 500-749 grams	Diagnosis	ICD-10-CM
P0513	Newborn small for gestational age, 750-999 grams	Diagnosis	ICD-10-CM
P0514	Newborn small for gestational age, 1000-1249 grams	Diagnosis	ICD-10-CM
P0515	Newborn small for gestational age, 1250-1499 grams	Diagnosis	ICD-10-CM
P0516	Newborn small for gestational age, 1500-1749 grams	Diagnosis	ICD-10-CM
P0517	Newborn small for gestational age, 1750-1999 grams	Diagnosis	ICD-10-CM
P0518	Newborn small for gestational age, 2000-2499 grams	Diagnosis	ICD-10-CM
P0519	Newborn small for gestational age, other	Diagnosis	ICD-10-CM