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	Low Birth Weight 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	This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define low birth weight in this request. 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
Outcome	Low birth weight
Algorithm to Define Outcome	The low birth weight outcome is defined as one International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code for low birth weight 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 Low Birth Weight in this Request

Code	Description	Code Category	Code Type
Low birth weight			
P07	Disorders of newborn related to short gestation and low birth weight, not elsewhere classified	Diagnosis	ICD-10-CM
P070	Extremely low birth weight newborn	Diagnosis	ICD-10-CM
P0700	Extremely low birth weight newborn, unspecified weight	Diagnosis	ICD-10-CM
P0701	Extremely low birth weight newborn, less than 500 grams	Diagnosis	ICD-10-CM
P0702	Extremely low birth weight newborn, 500-749 grams	Diagnosis	ICD-10-CM
P0703	Extremely low birth weight newborn, 750-999 grams	Diagnosis	ICD-10-CM
P071	Other low birth weight newborn	Diagnosis	ICD-10-CM
P0710	Other low birth weight newborn, unspecified weight	Diagnosis	ICD-10-CM
P0714	Other low birth weight newborn, 1000-1249 grams	Diagnosis	ICD-10-CM
P0715	Other low birth weight newborn, 1250-1499 grams	Diagnosis	ICD-10-CM
P0716	Other low birth weight newborn, 1500-1749 grams	Diagnosis	ICD-10-CM
P0717	Other low birth weight newborn, 1750-1999 grams	Diagnosis	ICD-10-CM
P0718	Other low birth weight newborn, 2000-2499 grams	Diagnosis	ICD-10-CM
P072	Extreme immaturity	Diagnosis	ICD-10-CM