

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	COVID-19 Diagnosis Algorithm Defined in "Racial Differences in COVID-19 Outcomes (2020-2021)"
Request ID	cder_mpl2p_wp033
Description	<p>This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes, and algorithms used to define COVID-19 Diagnosis in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/assessments/drugs/individual-drug-queries/comparison-race-and-ethnicity-covid-19-testing</p>
Outcome	COVID-19 Diagnosis
Algorithm to Define Outcome	COVID-19 Diagnosis outcomes were defined using ICD-10-CM diagnosis codes that occurred in the inpatient care setting in the principal diagnosis position. An outcome of interest was included if the individual had no evidence of the outcome in any care setting in the six months (183 days) prior to the outcome of interest.
Query Period	April 1, 2020 - March 31, 2021
Request Send Date	July 11, 2022

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

List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define COVID-19 Diagnosis in this Request

Code	Description	Code Category	Code Type
U07.1	COVID-19, virus identified [code effective April 1, 2020]	Diagnosis	ICD-10-CM