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 Hospitalization Algorithm Defined in "COVID-19 Hospitalization and Severe COVID-19 Infection Following Proton Pump Inhibitor (PPI) Use in Patients with Gastroesophageal Reflux Disease (GERD): An Inverse Probability of Treatment Weighting Analysis"
Request ID	cder_mpl2r_wp018
Description	This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes and algorithms used to define COVID-19 hospitalization 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/covid-19-hospitalization-and-severe-covid-19-infection-0
Outcome	COVID-19 hospitalization
Algorithm to Define Outcome	The COVID-19 hospitalization outcome is defined as a COVID-19 diagnosis code (see Code List 1) in the inpatient (IP) care setting in any diagnosis position.
Query Period	April 1, 2020 - October 1, 2020
Request Send Date	June 1, 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) Diagnosis Codes Used to Define COVID-19 Diagnosis in this Request

Code	Description	Care Setting	Principal Diagnosis	Code Category	Code Type
U07.1	COVID-19	IP	Any	Diagnosis	ICD-10-CM