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	Constipation Algorithm Defined in "Risk of Gastrointestinal Hypomotility, Constipation, or GI Dysmotility with Serious Complications and Intentional Self-Harm in Individuals with Migraine Following Use of CGRP Inhibitors: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp065
Description	This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes and algorithms used to define constipation 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-gastrointestinal-hypomotility-constipation-or-gi
Outcome	Constipation
Algorithm to Define Outcome	The constipation outcome is defined as an inpatient diagnosis of constipation. An outcome is considered valid only if, during the hospitalization period, there is no diagnosis of colon or rectal cancer, ovarian cancer, malignant neoplasm of the genitourinary organs, Crohn's disease or ulcerative colitis, cancer of the small intestine, malignant neoplasm of the retroperitoneum or peritoneum, secondary malignant neoplasm of the peritoneum, peritoneal adhesions, or epigastric or upper quadrant pain with intestinal obstruction, and there were no major abdominal surgeries performed during the two week period prior to hospitalization through the end of hospitalization.
Query Period	May 1, 2018 – June 30, 2025
Request Send Date	February 9, 2026

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 Constipation in this Request

Code	Description	Code Category	Code Type
Constipation			
K59.0	Constipation	10	DX
K59.00	Constipation, unspecified	10	DX
K59.01	Slow transit constipation	10	DX
K59.02	Outlet dysfunction constipation	10	DX
K59.03	Drug induced constipation	10	DX
K59.04	Chronic idiopathic constipation	10	DX
K59.09	Other constipation	10	DX