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	Seizure Algorithm Defined in "Seizure following Ranolazine Use: a Self-Controlled Risk Interval Analysis"
Request ID	cder_mpl2p_wp002_nsdp_v01, cder_mpl2p_wp006_nsdp_v01
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define seizures in these requests. For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analyses, see the Modular Program reports here: https://www.sentinelinitiative.org/drugs/assessments/ranexa-ranolazine-and-seizures.
Outcome	Seizures
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define seizure in the Inpatient in any diagnosis position or Emergency Department care setting
Query Period	2006-2017
Request Send Date	November 18, 2016; November 9, 2017

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

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Seizures in this Request

ICD-9-CM Codes	Description
345	Epilepsy and recurrent seizures
345*	Epilepsy and recurrent seizures
345**	Epilepsy and recurrent seizures
780.3	Convulsions
780.3*	Convulsions
333.2	Myoclonus

Note: Codes containing "*" indicate wildcards. Wildcards are used to represent a digit 0-9 or a letter A-Z. Wildcards are always indicative of one character. For example, "250*" will always expand into a four-digit code, never a five-digit code, while "250**" will always expand into a five-digit code.