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	Angioedema Algorithm Defined in "Angioedema following Sacubitril/Valsartan Use in Patients with Heart Failure: An Updated Propensity Score Matched Analysis"
Request ID	cder_mpl2r_wp032
Description	This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes and algorithm used to define angioedema in this request. For additional information about the algorithm and how they were defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/angioedema-following-sacubitrilvalsartan-use-patients-0
Outcomes	Angioedema
Algorithms to Define Outcomes	The primary outcome of interest, angioedema, is defined as evidence of one ICD-9-CM or ICD-10-CM diagnosis code from Code List 1 identified in an inpatient, emergency department, or outpatient encounter.
Query Period	July 7, 2015 - February 29, 2020
Request Send Date	January 18, 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

Code List 1. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Angioedema in this Request

Code	Description	Code Type	Code Category
995.1	Angioedema	ICD-9-CM	Diagnosis
T783XXA	Angioedema	ICD-10-CM	Diagnosis