

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	Ventricular Arrhythmia Algorithm Defined in "Cardiovascular Outcomes following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
Request ID	cder_mpl1r_wp228
Description	<p>This report lists International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define ventricular arrhythmia 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 analysis, see the analysis page here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/cardiovascular-outcomes-following-percutaneous-transluminal</p>
Outcome	Ventricular arrhythmia
Algorithm to Define Outcome	Ventricular arrhythmia outcomes were defined using ICD-9-CM and ICD-10-CM codes that occurred in an inpatient or emergency department care setting within 365 days following and including the index PTSMA procedure date.
Query Period	January 1, 2014 - December 31, 2021
Request Send Date	August 5, 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, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Ventricular Arrhythmia in this Request

Code	Description	Code Category	Code Type
Ventricular Arrhythmia			
427.0	Paroxysmal supraventricular tachycardia	Diagnosis	ICD-9-CM
427.1	Paroxysmal ventricular tachycardia	Diagnosis	ICD-9-CM
427.2	Unspecified paroxysmal tachycardia	Diagnosis	ICD-9-CM
427.3	Atrial fibrillation and flutter	Diagnosis	ICD-9-CM
427.4	Ventricular fibrillation and flutter	Diagnosis	ICD-9-CM
427.41	Ventricular fibrillation	Diagnosis	ICD-9-CM
427.42	Ventricular flutter	Diagnosis	ICD-9-CM
427.5	Cardiac arrest	Diagnosis	ICD-9-CM
427.6	Premature beats	Diagnosis	ICD-9-CM
427.8	Other specified cardiac dysrhythmias	Diagnosis	ICD-9-CM
427.89	Other specified cardiac dysrhythmias	Diagnosis	ICD-9-CM
427.9	Unspecified cardiac dysrhythmia	Diagnosis	ICD-9-CM
I46.2	Cardiac arrest due to underlying cardiac condition	Diagnosis	ICD-10-CM
I46.8	Cardiac arrest due to other underlying condition	Diagnosis	ICD-10-CM
I46.9	Cardiac arrest, cause unspecified	Diagnosis	ICD-10-CM
I47.0	Re-entry ventricular arrhythmia	Diagnosis	ICD-10-CM
I47.1	Supraventricular tachycardia	Diagnosis	ICD-10-CM
I47.2	Ventricular tachycardia	Diagnosis	ICD-10-CM
I47.9	Paroxysmal tachycardia, unspecified	Diagnosis	ICD-10-CM
I49.01	Ventricular fibrillation	Diagnosis	ICD-10-CM
I49.02	Ventricular flutter	Diagnosis	ICD-10-CM
I49.2	Junctional premature depolarization	Diagnosis	ICD-10-CM
I49.8	Other specified cardiac arrhythmias	Diagnosis	ICD-10-CM
I49.9	Cardiac arrhythmia, unspecified	Diagnosis	ICD-10-CM