

## 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

<b>Title</b>	Septal Myectomy Algorithm Defined in "Cardiovascular Outcomes following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
<b>Request ID</b>	cder_mpl1r_wp228
<b>Description</b>	<p>This report lists International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes and algorithms used to define septal myectomy 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:  <a href="https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/cardiovascular-outcomes-following-percutaneous-transluminal">https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/cardiovascular-outcomes-following-percutaneous-transluminal</a></p>
<b>Outcome</b>	Septal myectomy
<b>Algorithm to Define Outcome</b>	Septal myectomy outcomes were defined using ICD-9-CM, ICD-10-PCS, and CPT-4 codes that occurred in an inpatient care setting within 365 days following and including the index PTSMA procedure date.
<b>Query Period</b>	January 1, 2014 - December 31, 2021
<b>Request Send Date</b>	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), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define Septal Myectomy in this Request

Code	Description	Code Category	Code Type
<b>Septal Myectomy</b>			
37.33	Excision or destruction of other lesion or tissue of heart, open approach	Procedure	ICD-9-CM
02550ZZ	Destruction of Atrial Septum, Open Approach	Procedure	ICD-10-PCS
025M0ZZ	Destruction of Ventricular Septum, Open Approach	Procedure	ICD-10-PCS
02B50ZZ	Excision of Atrial Septum, Open Approach	Procedure	ICD-10-PCS
02BM0ZZ	Excision of Ventricular Septum, Open Approach	Procedure	ICD-10-PCS
33416	Ventriculomyotomy (-myectomy) for idiopathic hypertrophic subaortic stenosis (eg, asymmetric septal hypertrophy)	Procedure	CPT-4