

## 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>	Heart Failure 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) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define heart failure 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>	Heart failure
<b>Algorithm to Define Outcome</b>	Heart failure 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.
<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) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Heart Failure in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
<b>Heart Failure</b>			
402.01	Malignant hypertensive heart disease with heart failure	Diagnosis	ICD-9-CM
402.11	Benign hypertensive heart disease with heart failure	Diagnosis	ICD-9-CM
402.91	Hypertensive heart disease, unspecified, with heart failure	Diagnosis	ICD-9-CM
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
428.41	Acute combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.31	Acute diastolic heart failure	Diagnosis	ICD-9-CM
428.43	Acute on chronic combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.33	Acute on chronic diastolic heart failure	Diagnosis	ICD-9-CM
428.23	Acute on chronic systolic heart failure	Diagnosis	ICD-9-CM
428.21	Acute systolic heart failure	Diagnosis	ICD-9-CM
428.42	Chronic combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.32	Chronic diastolic heart failure	Diagnosis	ICD-9-CM
428.22	Chronic systolic heart failure	Diagnosis	ICD-9-CM
428.4	Combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.0	Congestive heart failure, unspecified	Diagnosis	ICD-9-CM
428.3	Diastolic heart failure	Diagnosis	ICD-9-CM
428	Heart failure	Diagnosis	ICD-9-CM
428.1	Left heart failure	Diagnosis	ICD-9-CM
428.2	Systolic heart failure	Diagnosis	ICD-9-CM
428.40	Unspecified combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.30	Unspecified diastolic heart failure	Diagnosis	ICD-9-CM
428.9	Unspecified heart failure	Diagnosis	ICD-9-CM
428.20	Unspecified systolic heart failure	Diagnosis	ICD-9-CM
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.31	Acute diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.33	Acute on chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.23	Acute on chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.21	Acute systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
I50.32	Chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.22	Chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.9	Heart failure, unspecified	Diagnosis	ICD-10-CM
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	Diagnosis	ICD-10-CM
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	Diagnosis	ICD-10-CM
I11.0	Hypertensive heart disease with heart failure	Diagnosis	ICD-10-CM
I50.1	Left ventricular failure	Diagnosis	ICD-10-CM
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.30	Unspecified diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.20	Unspecified systolic (congestive) heart failure	Diagnosis	ICD-10-CM
398.91	Rheumatic heart failure (congestive)	Diagnosis	ICD-10-CM
I09.81	Rheumatic heart failure	Diagnosis	ICD-10-CM
I50.810	Right heart failure, unspecified	Diagnosis	ICD-10-CM
I50.811	Acute right heart failure	Diagnosis	ICD-10-CM
I50.812	Chronic right heart failure	Diagnosis	ICD-10-CM
I50.813	Acute on chronic right heart failure	Diagnosis	ICD-10-CM
I50.814	Right heart failure due to left heart failure	Diagnosis	ICD-10-CM
I50.82	Biventricular heart failure	Diagnosis	ICD-10-CM
I50.83	High output heart failure	Diagnosis	ICD-10-CM
I50.84	End stage heart failure	Diagnosis	ICD-10-CM
I50.89	Other heart failure	Diagnosis	ICD-10-CM
I42.5	Other restrictive cardiomyopathy	Diagnosis	ICD-10-CM
I42.8	Other cardiomyopathies	Diagnosis	ICD-10-CM
P29.0	Neonatal cardiac failure	Diagnosis	ICD-10-CM
I42.0	Dilated cardiomyopathy	Diagnosis	ICD-10-CM
I43	Cardiomyopathy in diseases classified elsewhere	Diagnosis	ICD-10-CM
I42.7	Cardiomyopathy due to drug and external agent	Diagnosis	ICD-10-CM
I42.6	Alcoholic cardiomyopathy	Diagnosis	ICD-10-CM