



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	Heart Failure Algorithm Defined in "Acute Myocardial Infarction and Heart Failure following Saxagliptin or Sitagliptin Use: a Propensity Score Matched Analysis"
Request ID	cder_mpl2r_wp008_nsdv_v02
Description	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis 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 inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/drugs/assessments/acute-myocardial-infarction-and-hospitalized-heart-failure-following-saxagliptin</p>
Outcome	Heart failure
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define heart failure as the principal diagnosis in the inpatient care setting.
Query Period	October 1, 2006 - September 30, 2015
Request Send Date	February 14, 2019



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 Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Heart Failure in this Request

Codes	Description	Code Type
402.01	Malignant hypertensive heart disease with heart failure	ICD-9-CM
402.11	Benign hypertensive heart disease with heart failure	ICD-9-CM
402.91	Unspecified hypertensive heart disease with heart failure	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	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	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	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	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	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	ICD-9-CM
428	Heart failure	ICD-9-CM
428.0	Congestive heart failure, unspecified	ICD-9-CM
428.1	Left heart failure	ICD-9-CM
428.2	Systolic heart failure	ICD-9-CM
428.20	Systolic heart failure, unspecified	ICD-9-CM
428.21	Acute systolic heart failure	ICD-9-CM
428.22	Chronic systolic heart failure	ICD-9-CM
428.23	Acute on chronic systolic heart failure	ICD-9-CM
428.3	Diastolic heart failure	ICD-9-CM
428.30	Diastolic heart failure, unspecified	ICD-9-CM
428.31	Acute diastolic heart failure	ICD-9-CM
428.32	Chronic diastolic heart failure	ICD-9-CM
428.33	Acute on chronic diastolic heart failure	ICD-9-CM
428.4	Combined systolic and diastolic heart failure	ICD-9-CM
428.40	Combined systolic and diastolic heart failure, unspecified	ICD-9-CM
428.41	Acute combined systolic and diastolic heart failure	ICD-9-CM
428.42	Chronic combined systolic and diastolic heart failure	ICD-9-CM
428.43	Acute on chronic combined systolic and diastolic heart failure	ICD-9-CM
428.9	Heart failure, unspecified	ICD-9-CM