

## 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>	Angioedema and Serious Angioedema Algorithms Defined in "Angioedema following Sacubitril/Valsartan Use in Patients with Heart Failure: A Propensity Score Analysis"
<b>Request ID</b>	cder_mpl2r_wp016, cder_mpl2p_wp021
<b>Description</b>	<p>This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) diagnosis and procedure codes and algorithms used to define angioedema and serious angioedema in these requests.</p> <p>For additional information about the algorithms and how they were defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here:  <a href="https://www.sentinelinitiative.org/assessments/drugs/angioedema-following-sacubitrilvalsartan-use-patients-heart-failure-propensity">https://www.sentinelinitiative.org/assessments/drugs/angioedema-following-sacubitrilvalsartan-use-patients-heart-failure-propensity</a></p>
<b>Outcomes</b>	Angioedema and Serious Angioedema
<b>Algorithms to Define Outcomes</b>	<p>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.</p> <p>The secondary outcome of interest, serious angioedema, is defined as evidence of one ICD-9-CM or ICD-10-CM diagnosis code from Code List 1 identified in an inpatient or emergency department encounter AND evidence of one ICD-9-CM or ICD-10-CM diagnosis code or ICD-9-CM, ICD-10-PCS, CPT-4, or HCPCS procedure code used to define intensive care unit admission, intubation, tracheostomy, or laryngoscopy from Code List 2 within 2 days of qualifying angioedema diagnosis, including the date of diagnosis.</p>
<b>Query Period</b>	July 7, 2015 - February 29, 2020 (cder_mpl2r_wp016 and cder_mpl2p_wp021)
<b>Request Send Date</b>	November 13, 2020 (cder_mpl2r_wp016); January 13, 2021 (cder_mpl2p_wp021)

## 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**

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<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
995.1	Angioedema	ICD-9-CM	Diagnosis
T783XXA	Angioedema	ICD-10-CM	Diagnosis

**Code List 2. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes and ICD-9-CM, International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Procedure Codes Used to Define Intensive Care Unit Admission, Intubation, Tracheostomy, or Laryngoscopy in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
09HN7BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
09HN8BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0B110F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Open Approach	ICD-10-PCS	Procedure
0B110Z4	Bypass Trachea to Cutaneous, Open Approach	ICD-10-PCS	Procedure
0B113F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Approach	ICD-10-PCS	Procedure
0B113Z4	Bypass Trachea to Cutaneous, Percutaneous Approach	ICD-10-PCS	Procedure
0B114F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B114Z4	Bypass Trachea to Cutaneous, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B710DZ	Dilation of Trachea with Intraluminal Device, Open Approach	ICD-10-PCS	Procedure
0B710ZZ	Dilation of Trachea, Open Approach	ICD-10-PCS	Procedure
0B713DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Approach	ICD-10-PCS	Procedure
0B713ZZ	Dilation of Trachea, Percutaneous Approach	ICD-10-PCS	Procedure
0B714DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B714ZZ	Dilation of Trachea, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B717DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B717ZZ	Dilation of Trachea, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B718DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B718ZZ	Dilation of Trachea, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0B720DZ	Dilation of Carina with Intraluminal Device, Open Approach	ICD-10-PCS	Procedure
0B720ZZ	Dilation of Carina, Open Approach	ICD-10-PCS	Procedure
0B723DZ	Dilation of Carina with Intraluminal Device, Percutaneous Approach	ICD-10-PCS	Procedure
0B723ZZ	Dilation of Carina, Percutaneous Approach	ICD-10-PCS	Procedure
0B724DZ	Dilation of Carina with Intraluminal Device, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B724ZZ	Dilation of Carina, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0B727DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B727ZZ	Dilation of Carina, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B728DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0B728ZZ	Dilation of Carina, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0BH07DZ	Insertion of Intraluminal Device into Tracheobronchial Tree, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0BH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0BH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0BJ14ZZ	Inspection of Trachea, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0BJ18ZZ	Inspection of Trachea, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0BQ10ZZ	Repair Trachea, Open Approach	ICD-10-PCS	Procedure
0BQ13ZZ	Repair Trachea, Percutaneous Approach	ICD-10-PCS	Procedure
0BQ14ZZ	Repair Trachea, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0BQ17ZZ	Repair Trachea, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0BQ18ZZ	Repair Trachea, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure

**Code List 2. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes and ICD-9-CM, International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Procedure Codes Used to Define Intensive Care Unit Admission, Intubation, Tracheostomy, or Laryngoscopy in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
0BQ20ZZ	Repair Carina, Open Approach	ICD-10-PCS	Procedure
0BQ23ZZ	Repair Carina, Percutaneous Approach	ICD-10-PCS	Procedure
0BQ24ZZ	Repair Carina, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
0BQ27ZZ	Repair Carina, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
0BQ28ZZ	Repair Carina, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
OCHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
OCHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
OCJS4ZZ	Inspection of Larynx, Percutaneous Endoscopic Approach	ICD-10-PCS	Procedure
OCJS8ZZ	Inspection of Larynx, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
ODH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
ODH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
ODL57DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
ODL58DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
0WHQ7YZ	Insertion of Other Device into Respiratory Tract, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
31.1	Tracheostomy	ICD-9-CM	Procedure
31.2	Tracheostomy	ICD-9-CM	Procedure
31.21	Tracheostomy	ICD-9-CM	Procedure
31.29	Tracheostomy	ICD-9-CM	Procedure
31.42	Laryngoscopy	ICD-9-CM	Procedure
31.99	Intubation	ICD-9-CM	Procedure
31231	Laryngoscopy	CPT-4	Procedure
31502	Intubation	CPT-4	Procedure
31505	Laryngoscopy	CPT-4	Procedure
31525	Laryngoscopy	CPT-4	Procedure
31526	Laryngoscopy	CPT-4	Procedure
31527	Laryngoscopy	CPT-4	Procedure
31528	Laryngoscopy	CPT-4	Procedure
31529	Laryngoscopy	CPT-4	Procedure
31560	Laryngoscopy	CPT-4	Procedure
31561	Laryngoscopy	CPT-4	Procedure
31603	Tracheostomy	CPT-4	Procedure
31605	Tracheostomy	CPT-4	Procedure
31610	Tracheostomy	CPT-4	Procedure
31612	Tracheostomy	CPT-4	Procedure
31615	Tracheostomy	CPT-4	Procedure
3E1F78Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening	ICD-10-PCS	Procedure
3E1F88Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening Endoscopic	ICD-10-PCS	Procedure
5A1935Z	Respiratory Ventilation, Less than 24 Consecutive Hours	ICD-10-PCS	Procedure

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<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
5A1945Z	Respiratory Ventilation, 24-96 Consecutive Hours	ICD-10-PCS	Procedure
5A1955Z	Respiratory Ventilation, Greater than 96 Consecutive Hours	ICD-10-PCS	Procedure
91000	Intubation	CPT-4	Procedure
96	Intubation	ICD-9-CM	Procedure
96	Intubation	ICD-9-CM	Procedure
96.01	Intubation	ICD-9-CM	Procedure
96.02	Intubation	ICD-9-CM	Procedure
96.03	Intubation	ICD-9-CM	Procedure
96.04	Intubation	ICD-9-CM	Procedure
96.05	Intubation	ICD-9-CM	Procedure
96.06	Intubation	ICD-9-CM	Procedure
96.56	Intubation	ICD-9-CM	Procedure
96.7	Intubation	ICD-9-CM	Procedure
96.7	Intubation	ICD-9-CM	Procedure
96.71	Intubation	ICD-9-CM	Procedure
96.72	Intubation	ICD-9-CM	Procedure
99220	ICU Admission	CPT-4	Procedure
99221	ICU Admission	CPT-4	Procedure
99222	ICU Admission	CPT-4	Procedure
99223	ICU Admission	CPT-4	Procedure
99224	ICU Admission	CPT-4	Procedure
99225	ICU Admission	CPT-4	Procedure
99226	ICU Admission	CPT-4	Procedure
99291	ICU Admission	CPT-4	Procedure
99292	ICU Admission	CPT-4	Procedure
A0396	Intubation	HCPCS	Procedure
V44.0	Tracheostomy	ICD-9-CM	Diagnosis
V55.0	Tracheostomy	ICD-9-CM	Diagnosis
Z43.0	Encounter for Attention to Tracheostomy	ICD-10-CM	Diagnosis
Z93.0	Tracheostomy Status	ICD-10-CM	Diagnosis