

## 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>	Permanent Pacemaker Placement Algorithm Defined in "Cardiovascular Outcomes following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: An Updated Descriptive Analysis"
<b>Request ID</b>	cder_mpl1r_wp240
<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 permanent pacemaker placement 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">https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/cardiovascular-outcomes-following-percutaneous</a></p>
<b>Outcome</b>	Permanent pacemaker placement
<b>Algorithm to Define Outcome</b>	Permanent pacemaker placement outcomes were defined using ICD-9-CM, ICD-10-PCS, and CPT-4 codes that occurred in any care setting within 90 days following and including the index PTSMA procedure date.
<b>Query Period</b>	January 1, 2016 - June 30, 2022
<b>Request Send Date</b>	December 6, 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 Permanent Pacemaker Placement in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
<b>Permanent Pacemaker Placement</b>			
37.80	Insertion of permanent pacemaker, initial or replacement, type of device not specified	Procedure	ICD-9-CM
37.81	Initial insertion of single-chamber device, not specified as rate responsive	Procedure	ICD-9-CM
37.82	Initial insertion of single-chamber device, rate responsive	Procedure	ICD-9-CM
37.83	Initial insertion of dual-chamber device	Procedure	ICD-9-CM
OJH604Z	Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH605Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH606Z	Insertion of Pacemaker, Dual Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH60PZ	Insertion of Cardiac Rhythm Related Device into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH634Z	Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH635Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH636Z	Insertion of Pacemaker, Dual Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH63PZ	Insertion of Cardiac Rhythm Related Device into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH804Z	Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH805Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH806Z	Insertion of Pacemaker, Dual Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH80PZ	Insertion of Cardiac Rhythm Related Device into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH834Z	Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH835Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH836Z	Insertion of Pacemaker, Dual Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH83PZ	Insertion of Cardiac Rhythm Related Device into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	Procedure	CPT-4
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular	Procedure	CPT-4

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	Procedure	CPT-4
33213	Insertion of pacemaker pulse generator only; with existing dual leads	Procedure	CPT-4
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator	Procedure	CPT-4
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber	Procedure	CPT-4
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed	Procedure	CPT-4
33271	Insertion of subcutaneous implantable defibrillator electrode	Procedure	CPT-4
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode	Procedure	CPT-3
0320T	Insertion of subcutaneous defibrillator electrode	Procedure	CPT-4
0321T	Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode	Procedure	CPT-4
33200	Insertion of permanent pacemaker with epicardial electrode(s); by thoracotomy	Procedure	CPT-4
33201	Insertion of permanent pacemaker with epicardial electrode(s); by xiphoid approach	Procedure	CPT-4
33245	Insertion of epicardial single or dual chamber pacing cardioverter-defibrillator electrodes by thoracotomy;	Procedure	CPT-4
33247	Insertion or replacement of implantable cardioverter-defibrillator lead(s), by other than thoracotomy;	Procedure	CPT-4
71090	Insertion pacemaker, fluoroscopy and radiography, radiological supervision and interpretation	Procedure	CPT-4
00.50	Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (CRT-P)	Procedure	ICD-9-CM
00.51	Implantation of cardiac resynchronization defibrillator, total system (CRT-D)	Procedure	ICD-9-CM
00.52	Implantation or replacement of transvenous lead (electrode) into left ventricular coronary venous system	Procedure	ICD-9-CM
00.53	Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (CRT-P)	Procedure	ICD-9-CM
34.85	Implantation of diaphragmatic pacemaker	Procedure	ICD-9-CM
37.78	Insertion of temporary transvenous pacemaker system	Procedure	ICD-9-CM
37.8	Insertion, replacement, removal and revision of pacemaker device	Procedure	ICD-9-CM
37.80	Insertion of permanent pacemaker, initial or replacement, type of device not specified	Procedure	ICD-9-CM
37.81	Initial insertion of single-chamber device, not specified as rate responsive	Procedure	ICD-9-CM
37.82	Initial insertion of single-chamber device, rate responsive	Procedure	ICD-9-CM



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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
37.83	Initial insertion of dual-chamber device	Procedure	ICD-9-CM
37.94	Implantation or replacement of automatic cardioverter/ defibrillator, total system (AICD)	Procedure	ICD-9-CM
37.95	Implantation of automatic cardioverter/defibrillator leads(s) only	Procedure	ICD-9-CM
02H40JZ	Insertion of Pacemaker Lead into Coronary Vein, Open Approach	Procedure	ICD-10-PCS
02H40KZ	Insertion of Defibrillator Lead into Coronary Vein, Open Approach	Procedure	ICD-10-PCS
02H43JZ	Insertion of Pacemaker Lead into Coronary Vein, Percutaneous Approach	Procedure	ICD-10-PCS
02H43KZ	Insertion of Defibrillator Lead into Coronary Vein, Percutaneous Approach	Procedure	ICD-10-PCS
02H43MZ	Insertion of Cardiac Lead into Coronary Vein, Percutaneous Approach	Procedure	ICD-10-PCS
02H44JZ	Insertion of Pacemaker Lead into Coronary Vein, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02H44KZ	Insertion of Defibrillator Lead into Coronary Vein, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02H60JZ	Insertion of Pacemaker Lead into Right Atrium, Open Approach	Procedure	ICD-10-PCS
02H60KZ	Insertion of Defibrillator Lead into Right Atrium, Open Approach	Procedure	ICD-10-PCS
02H63JZ	Insertion of Pacemaker Lead into Right Atrium, Percutaneous Approach	Procedure	ICD-10-PCS
02H63KZ	Insertion of Defibrillator Lead into Right Atrium, Percutaneous Approach	Procedure	ICD-10-PCS
02H64JZ	Insertion of Pacemaker Lead into Right Atrium, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02H64KZ	Insertion of Defibrillator Lead into Right Atrium, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02H70KZ	Insertion of Defibrillator Lead into Left Atrium, Open Approach	Procedure	ICD-10-PCS
02H73KZ	Insertion of Defibrillator Lead into Left Atrium, Percutaneous Approach	Procedure	ICD-10-PCS
02H74KZ	Insertion of Defibrillator Lead into Left Atrium, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02HK0JZ	Insertion of Pacemaker Lead into Right Ventricle, Open Approach	Procedure	ICD-10-PCS
02HK0KZ	Insertion of Defibrillator Lead into Right Ventricle, Open Approach	Procedure	ICD-10-PCS
02HK3JZ	Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Approach	Procedure	ICD-10-PCS
02HK3KZ	Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Approach	Procedure	ICD-10-PCS
02HK4JZ	Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02HK4KZ	Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02HL0JZ	Insertion of Pacemaker Lead into Left Ventricle, Open Approach	Procedure	ICD-10-PCS
02HL0KZ	Insertion of Defibrillator Lead into Left Ventricle, Open Approach	Procedure	ICD-10-PCS
02HL3JZ	Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Approach	Procedure	ICD-10-PCS
02HL3KZ	Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach	Procedure	ICD-10-PCS
02HL4JZ	Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02HL4KZ	Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
02HN0KZ	Insertion of Defibrillator Lead into Pericardium, Open Approach	Procedure	ICD-10-PCS

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
02HN3KZ	Insertion of Defibrillator Lead into Pericardium, Percutaneous Approach	Procedure	ICD-10-PCS
02HN4KZ	Insertion of Defibrillator Lead into Pericardium, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0BHT0MZ	Insertion of Diaphragmatic Pacemaker Lead into Diaphragm, Open Approach	Procedure	ICD-10-PCS
0BHT3MZ	Insertion of Diaphragmatic Pacemaker Lead into Diaphragm, Percutaneous Approach	Procedure	ICD-10-PCS
0BHT4MZ	Insertion of Diaphragmatic Pacemaker Lead into Diaphragm, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0JH604Z	Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH605Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH606Z	Insertion of Pacemaker, Dual Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH607Z	Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH608Z	Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH609Z	Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH60PZ	Insertion of Cardiac Rhythm Related Device into Chest Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH634Z	Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH635Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH636Z	Insertion of Pacemaker, Dual Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH637Z	Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH638Z	Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH639Z	Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH63PZ	Insertion of Cardiac Rhythm Related Device into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
0JH804Z	Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH805Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
0JH806Z	Insertion of Pacemaker, Dual Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
OJH807Z	Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH808Z	Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH809Z	Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH80PZ	Insertion of Cardiac Rhythm Related Device into Abdomen Subcutaneous Tissue and Fascia, Open Approach	Procedure	ICD-10-PCS
OJH834Z	Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH835Z	Insertion of Pacemaker, Single Chamber Rate Responsive into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH836Z	Insertion of Pacemaker, Dual Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH837Z	Insertion of Cardiac Resynchronization Pacemaker Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH838Z	Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH839Z	Insertion of Cardiac Resynchronization Defibrillator Pulse Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS
OJH83PZ	Insertion of Cardiac Rhythm Related Device into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	Procedure	ICD-10-PCS