

Cigna Medical Coverage Policies - Pacemaker Guidelines for Cardiac Implantable Device (CID)

Effective July 1, 2023



Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the [Cigna CPT code list](#) for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

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Table of Contents

Guideline	Page
General Information.....	3
Abbreviations.....	4
Glossary.....	5
Preface to the Cardiac Implantable Device (CID) guideline.....	7
General information (CRID-1).....	10
Pacemaker Devices.....	12
Definite indications for permanent pacemaker implantation (CRID-7).....	13
Reasonable indications for permanent pacemaker implantation (CRID-8).....	15
Permanent pacemaker implantation - Non-indications (CRID-9).....	17
Leadless pacemaker (CRID-11.1).....	18
References.....	19
References.....	20

General Information

Guideline	Page
Abbreviations.....	4
Glossary.....	5
Preface to the Cardiac Implantable Device (CID) guideline.....	7
General information (CRID-1).....	10

Abbreviations

CID

v2.0.2023

- **ACE inhibitor** — Angiotensin-converting enzyme inhibitor
- **AMI** — Acute myocardial infarction
- **ARVC** — Arrhythmogenic right ventricular cardiomyopathy
- **AV** — Atrioventricular
- **CC** — Complications/comorbid conditions
- **CHF** — Congestive heart failure
- **CM** — Cardiomyopathy
- **CRT** — Cardiac resynchronization therapy
- **EP** — Electrophysiology
- **GDMT** — Guideline-directed medical therapy
- **HCM** — Hypertrophic cardiomyopathy
- **ICD** — Implantable cardioverter defibrillator
- **LBBB** — Left bundle branch block
- **LV** — Left ventricle
- **LVEF** — Left ventricular ejection fraction
- **MCC** — Major complications/comorbid conditions
- **MI** — Myocardial infarction
- **NCCM** — Non-compaction cardiomyopathy
- **NYHA** — New York Heart Association functional classification
- **RBBB** — Right bundle branch block
- **RV** — Right ventricle
- **TAVR** — Transcatheter aortic valve replacement
- **VF** — Ventricular fibrillation
- **VT** — Ventricular tachycardia

Glossary

CID

v2.0.2023

- **NYHA Heart Failure Definitions** — **class I** - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
class II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
class IV - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients
- **Abnormal blood pressure response to exercise** — Flat response/failure to augment; rise then fall during exercise; vasoactive cardiovascular drugs may result in an abnormal blood pressure response to exercise
- **Ambulatory class IV CHF** — Class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT
- **Incessant VT:** — Frequent recurrences of ongoing hemodynamically stable VT
- **Hypertrophic cardiomyopathy** — Hypertrophic Cardiomyopathy (HCM) is a clinical diagnosis, established by imaging with 2D echocardiography or cardiovascular magnetic resonance (CMR) showing a maximal end-diastolic wall thickness of ≥ 15 mm anywhere in the left ventricle, in the absence of another cause of hypertrophy in adults. More limited hypertrophy (13–14 mm) can be diagnostic, particularly when present in family members of a patient with HCM or in conjunction with a positive genetic test, and/or associated with typical dynamic outflow obstruction, or distinctly abnormal ECG patterns.
- **Long QT Syndrome (LQTS):** — A congenital disorder characterized by a prolongation of the QT interval on ECG and a propensity to ventricular tachyarrhythmias, which may lead to syncope, cardiac arrest, or sudden death. The QT interval on the ECG, measured from the beginning of the QRS complex to the end of the T wave, represents the duration of activation and recovery of the ventricular myocardium. QT intervals corrected for heart rate (QTc) longer than 0.44 seconds are generally considered abnormal, though a normal QTc can be more prolonged in females (up to 0.46 sec). The Bazett formula is the formula most commonly used to calculate the QTc, as follows: $QTc = QT / \sqrt{RR}$ (in seconds).
- **Non-Compaction Cardiomyopathy:** — A rare congenital cardiomyopathy that affects children and adults. It results from the failure of myocardial development during embryogenesis. It is also called spongiform cardiomyopathy. Symptoms are often a result of a poor pumping performance by the heart. The disease can be associated with other problems with the heart and the body.

- **Non-Sustained Ventricular Tachycardia (NSVT):** — Three or more consecutive ventricular beats at a rate of greater than 120 beats/min with a duration of less than 30 seconds
- **Optimal Medical Therapy:** — Three months of heart failure medications in maximally titrated doses as tolerated. These include beta blockers, ACE inhibitors or angiotensin II receptor blockers, and diuretics.
- **Structural Heart Disease:** — A structural or functional abnormality of the heart, or of the blood vessels supplying the heart, that impairs its normal functioning.

Preface to the Cardiac Implantable Device (CID) guideline

CID.AD.100.A

v2.0.2023

Guideline	Page
Guideline development (Preface-1).....	7
Benefits, coverage policies, and eligibility issues (Preface-2).....	8
Clinical information (Preface-3).....	8
References (Preface-4).....	9
Copyright information (Preface-5).....	9
Trademarks (Preface-6).....	9

Guideline development (Preface-1)

- The eviCore evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including CT, MRI, PET, and Radiation Oncology, Sleep Studies, and Cardiac and Spine interventions.
- eviCore healthcare reserves the right to change and update the guidelines. The guidelines undergo a formal review annually. eviCore's guidelines are based upon major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises, and input from health plans, practicing academic and community-based physicians.
- These guidelines are not intended to supersede or replace sound medical judgment, but instead should facilitate the identification of the most appropriate imaging procedure, given the patient's clinical condition. These guidelines are written to cover medical conditions as experienced by the majority of patients. However, these guidelines may not be applicable in certain clinical circumstances, and physician judgment can override the guidelines.
- Clinical decisions, including treatment decisions, are the responsibility of the patient and his/her provider. Clinicians are expected to use independent medical judgment which takes into account the clinical circumstances to determine patient management decisions.
- eviCore supports the Choosing Wisely® initiative (www.choosingwisely.org) by the American Board of Internal Medicine (ABIM) Foundation and many national physician organizations, to reduce the overuse of diagnostic tests that are low value, no value, or whose risks are greater than the benefits.
- eviCore's guidelines are based upon expert consensus and analysis reported by the following specialty societies, publications, studies and trials:
 - The American College of Cardiology (ACC)
 - The American Heart Association (AHA)
 - The Heart Rhythm Society (HRS)

- The Multicenter Automatic Defibrillator Implantation Trial (MADIT/MADIT-2)
- The Multicenter Unsustained Tachycardia Trial (MUSTT)
- The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT)
- The Resynchronization/defibrillation for Ambulatory Heart Failure Trial (RAFT)
- The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
- The Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction trial (REVERSE)
- Immediate Risk Stratification Improves Survival trial (IRIS)
- The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure trial (COMPANION)
- The Antiarrhythmic Versus Implantable Defibrillators trial (AVID)
- The Canadian Implantable Defibrillator Study (CIDS)
- The Cardiac Arrest Study Hamburg (CASH)

Benefits, coverage policies, and eligibility issues (Preface-2)

- Benefits, coverage policies, and eligibility issues pertaining to each Health Plan may take precedence over eviCore's guidelines. Providers are urged to obtain written instructions and requirements directly from each payer.
- Medicare Coverage Policies
 - For Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) may take precedence over eviCore's guidelines
 - Payors may choose to adopt other evidence-based guidelines (such as eviCore's guidelines) rather than using Local Coverage Determinations and other Medicare coverage policy
- Investigational and Experimental Studies
 - Certain imaging studies described in these guidelines are considered investigational by various payors, and their coverage policies may take precedence over eviCore's guidelines
- Clinical and Research Trials
 - Similar to investigational and experimental studies, clinical trial imaging requests will be considered to determine whether they meet health plan coverage and eviCore's evidence-based guidelines
- State and federal legislations may need to be considered in the review of advanced imaging requests

Clinical information (Preface-3)

- The philosophy behind eviCore guidelines entails using an evidence-based approach to determine the most appropriate procedure for each individual, at the most appropriate time in the diagnostic and treatment cycle.
- Procedures should be requested after initial consultation and physician treatment planning, and following full counseling of the individual.

- Current clinical information, which may include history, physical examination, symptoms, laboratory results, and imaging reports, are necessary for determining the medical necessity of implantable cardiac devices.
- The information provided to eviCore should have clinical relevance to the request.
- If the information provided makes no reference to the potential indication for the request, then the medical necessity for the procedure(s) cannot be supported.

References (Preface-4)

- References are available at the end of the guidelines

Copyright information (Preface-5)

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General information (CRID-1)

CID.AD.101.C

v2.0.2023

Guideline	Page
Procedure codes (CRID-1.1).....	10
Removal and replacement (CRID-1.2).....	11

Procedure codes (CRID-1.1)

Procedure description	CPT®
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	33206
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular	33207
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	33208
Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed	33274
Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	0795T
Transcatheter insertion of right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	0796T
Transcatheter insertion of right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0797T
Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	0801T
Transcatheter removal and replacement of right atrial pacemaker component	0802T

Procedure description	CPT®
Transcatheter removal and replacement of right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0803T

Removal and replacement (CRID-1.2)

- Generator replacement (CPT® 33227, 33228) with a same or similar device is indicated when:
 - Interrogation shows device is nearing Elective Replacement Indicator (ERI) or End of Life (EOL).
 - Interrogation report documents the device is not functioning correctly and requires replacement.

Pacemaker Devices

Guideline	Page
Definite indications for permanent pacemaker implantation (CRID-7)....	13
Reasonable indications for permanent pacemaker implantation (CRID-8).....	15
Permanent pacemaker implantation - Non-indications (CRID-9).....	17
Leadless pacemaker (CRID-11.1).....	18

Definite indications for permanent pacemaker implantation (CRID-7)

CID.PM.101.A

v2.0.2023

Guideline	Page
Symptomatic bradycardia (CRID-7.1).....	13
Symptomatic chronotropic incompetence (CRID-7.2).....	13
Indications for asymptomatic individuals (CRID-7.3).....	13
Prior to planned catheter ablation (CRID-7.4).....	14
Persistent second degree AV block (CRID-7.5).....	14
Syncope (CRID-7.6).....	14

Symptomatic bradycardia (CRID-7.1)

Permanent pacemaker implantation is indicated for symptomatic bradycardia for any of the following

- Frequent sinus pauses that produce symptoms
- Any degree of AV block producing symptoms
- Third-degree and advanced second-degree AV block at any anatomic level associated with ventricular arrhythmias presumed due to AV block.
- Any other medical conditions requiring drug therapy that results in symptomatic bradycardia (for example, beta blocker therapy in patients with prior myocardial infarction, or tachy-brady syndrome in atrial fibrillation)

Symptomatic chronotropic incompetence (CRID-7.2)

- Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence defined as limitations due to the inability to achieve 80% of maximum predicted heart rate (220-age)

Indications for asymptomatic individuals (CRID-7.3)

Permanent pacemaker implantation is indicated in asymptomatic individuals for **any** of the following:

- Third degree AV block
- Advanced second degree AV block (Mobitz type II) with intermittent third degree AV block
- Second degree AV block with documented periods of asystole ≥ 3.0 seconds
- Second degree AV block in awake, symptom-free individuals with atrial fibrillation with a documented pause of ≥ 5 seconds
- Alternating bundle branch block

- Second degree AV block at any anatomic level associated with neuromuscular diseases known to involve the heart
- Post Transcatheter Aortic Valve Replacement (TAVR) when there is documentation of **both**:
 - Pre-existing right bundle branch block (RBBB)
 - New conduction abnormality onset during or after (TAVR) such as:
 - Transient high-degree AV block
 - PR prolongation
 - QRS axis change

Background and supporting information

Prophylactic permanent pacemaker implantation is not indicated before TAVR in individuals with RBBB and no indication for permanent pacing. See Permanent Pacemaker **Implantation Non-indications (CRID-9.1)**.

Prior to planned catheter ablation (CRID-7.4)

- Permanent pacemaker implantation is indicated prior to a planned catheter ablation of the AV junction intended for a rate control strategy for management of atrial fibrillation.

Persistent second degree AV block (CRID-7.5)

- Permanent pacemaker implantation is indicated for persistent second degree AV block in the His-Purkinje system with alternating bundle branch block or third degree AV block within or below the His-Purkinje system after myocardial infarction.

Syncope (CRID-7.6)

- Permanent pacemaker implantation is indicated for syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of ≥ 3 seconds

Reasonable indications for permanent pacemaker implantation (CRID-8)

CID.PM.102.A

v2.0.2023

Guideline	Page
General considerations (CRID-8.1).....	15
Sinus node dysfunction (CRID-8.2).....	15
Syncope (CRID-8.3).....	15
Asymptomatic second degree AV block (CRID-8.4).....	16
First or second degree AV block (CRID-8.5).....	16
Symptomatic recurrent SVT (CRID-8.6).....	16
Relative bradycardia - Post-operative cardiac transplant (CRID-8.7).....	16
Incidental finding at electrophysiology (EP) study (CRID-8.8).....	16
Neuromuscular diseases known to involve the heart (CRID-8.9).....	16

General considerations (CRID-8.1)

For the reasonable or considered indications listed in this CRID-8 guideline, consensus opinion is less clear about permanent pacing in these settings, with evidence suggesting that device placement may be reasonable or may be considered

Sinus node dysfunction (CRID-8.2)

- Permanent pacemaker implantation is reasonable for individuals with sinus node dysfunction with a resting heart rate of less than 40 bpm when periodic symptomatic bradycardia is suspected

Syncope (CRID-8.3)

- Permanent pacemaker implantation may be reasonable or may be considered for individuals with syncope in the following settings
 - Syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered or provoked in electrophysiological studies
 - Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer
 - Significantly symptomatic neurocardiogenic syncope associated with Bradycardia documented spontaneously or at the time of tilt table testing
 - Syncope after cardiac transplantation even when bradyarrhythmia has not been documented

Asymptomatic second degree AV block (CRID-8.4)

- Permanent pacemaker implantation is reasonable for individuals with asymptomatic second degree AV block at intra- or infra- His levels found at electrophysiological study.

First or second degree AV block (CRID-8.5)

- Permanent pacemaker implantation is reasonable for individuals with first or second degree AV block with symptoms similar to those of pacemaker syndrome.

Symptomatic recurrent SVT (CRID-8.6)

- Permanent pacemaker implantation is reasonable for individuals with symptomatic, recurrent SVT that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects.

Relative bradycardia - Post-operative cardiac transplant (CRID-8.7)

- Permanent pacemaker implantation may be considered for individuals when relative bradycardia is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery from cardiac transplantation or in post-transplant syncope even if bradyarrhythmia has not been documented.

Incidental finding at electrophysiology (EP) study (CRID-8.8)

- Permanent pacemaker implantation may be reasonable for an incidental finding at electrophysiology study of a markedly prolonged HV interval (greater than or equal to 100 milliseconds) or non-physiological intra- or infra- Hisian block in asymptomatic patients.

Neuromuscular diseases known to involve the heart (CRID-8.9)

- Permanent pacemaker implantation may be considered for progressive neuromuscular diseases known to involve the heart with any degree of AV block (including first degree AV block) or any fascicular block, with or without symptoms, because there may be unpredictable progression of AV conduction disease. Progressive neuromuscular diseases known to involve the heart include:
 - Myotonic muscular dystrophy
 - Kearns-Sayre syndrome
 - Erb dystrophy (limb-girdle muscular dystrophy)
 - Peroneal muscular atrophy

Permanent pacemaker implantation - Non-indications (CRID-9)

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v2.0.2023

Permanent pacemaker implantation non-indications (CRID-9.1)

- Permanent pacemaker implantation is **not** indicated in any of the following settings:
 - Sinus node dysfunction in asymptomatic patients
 - Sinus node dysfunction in patients for whom the symptoms, suggestive of bradycardia, have been clearly documented to occur in the absence of bradycardia
 - Sinus node dysfunction in symptomatic patients due to nonessential drug therapy
 - Fascicular block without AV block or symptoms concerning for AV block
 - Incidentally noted hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
 - Asymptomatic first degree AV block
 - Asymptomatic type I second degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian
 - Permanent ventricular pacing not indicated for asymptomatic transient AV block in the absence of intraventricular conduction defects or in isolated single fascicular block
 - Permanent pacing not indicated for situational vasovagal syncope in which avoidance behavior is effective
 - Prophylactic permanent pacemaker implantation is not indicated before Transcatheter Aortic Valve Replacement (TAVR) in individuals with right bundle branch block (RBBB) and no indication for permanent pacing

Leadless pacemaker (CRID-11.1)

CID.PM.104.C

v2.0.2023

CPT® codes addressed

CPT® 33274, CPT® 0795T, CPT® 0796T, CPT® 0797T, CPT® 0801T, CPT® 0802T, CPT® 0803T

See Cigna Coverage Policy **0174 Cardiac Resynchronization Therapy (CRT) and Advanced Cardiac Pacing Technologies**

References

Guideline	Page
References.....	20

References

CID

v2.0.2023

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