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

Effective March 01, 2024

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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General Information

Abbreviations

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- **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

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Glossary

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- **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 = AT/square root of the R-R interval (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.

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- **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:** — Optimal medical therapy for heart failure should include a beta-blocker and one of the following:
  - ACE inhibitor
  - angiotensin II receptor blocker
  - angiotensin receptor-neprilysin inhibitor
- **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

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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)

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- 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)

Trademarks (Preface-6)

General information (CRID-1)

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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

Procedure description	CPT®
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; right atrial pacemaker component	0802T
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; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0803T
Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	0823T
Transcatheter removal of permanent single chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed	0824T
Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	0825T

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

Indications for Permanent Pacemaker Implantation (CRID-7)

CID.PM.105.A
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CPT® 33206, 33207, 33208

Sinus node dysfunction

Permanent pacemaker implantation is indicated for any of the following:

- Symptomatic sinus node dysfunction as evidenced by both of the following:
  - Documented sinus node dysfunction including one of the below:
    - Sinus bradycardia at rate <50 beats per minute
    - Sinus pauses >3 seconds
  - Symptoms attributable to sinus node dysfunction including one of the below:
    - Syncope or pre-syncope
    - Heart failure symptoms
    - Exertional fatigue and impaired exercise tolerance
- Sinus bradycardia at rate <40 beats per minute and symptoms possibly related to bradycardia
- Symptomatic sinus bradycardia (as defined above) as a consequence of guideline directed management and continued treatment is clinically necessary
- Symptoms attributable to bradycardia as listed above and evidence of tachy-brady syndrome (sinus bradycardia, ectopic atrial bradycardia, or sinus pause alternating with periods of atrial flutter or atrial fibrillation)
- Symptomatic chronotropic incompetence defined as limitations due to the inability to achieve 80% of maximum predicted heart rate (220-age)

Atrioventricular block (AVB)

Permanent pacemaker implantation is indicated for any of the following:

- AVB including one of the below with or without symptoms:
  - Second-degree Mobitz type II
  - High-grade (≥2 consecutive P waves at a constant physiologic rate that do not conduct to the ventricles)
  - Third-degree (complete heart block)
- Any degree of AVB with one of the following symptoms that are clearly attributable to the AVB:
  - Syncope or pre-syncope

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  - Heart failure symptoms
  - Exertional fatigue and impaired exercise tolerance
- Third-degree and advanced second-degree AV block at any anatomic level associated with sustained or non-sustained ventricular tachycardia (ventricular rhythm at rate >100 bpm lasting ≥3 consecutive beats) presumed due to AV block
- Marked first-degree AVB (PR interval >0.3 seconds) or second-degree AVB with symptoms similar to those of pacemaker syndrome
- Symptomatic AVB as a consequence of guideline directed management and continued treatment is clinically necessary
- Persistent or permanent atrial fibrillation and symptomatic bradycardia including one of the following:
  - Rate <50 beats per minute
  - Regular QRS intervals indicating complete AVB
- Second degree AV block with a documented pause of ≥5 seconds during waking in the presence of atrial fibrillation, with or without symptoms
- Second degree AV block with documented periods of asystole ≥3.0 seconds in the presence of sinus rhythm, with or without symptoms
- Second-degree AVB noted to be located at intra- or infra-His levels at electrophysiology study (EPS), with or without symptoms
- Any AVB indication listed above occurring after acute myocardial infarction that does not resolve within 5 days
- Congenital complete or high-degree AVB in the presence of any of the following:
  - Symptoms
  - Wide QRS escape rhythm
  - Mean daytime heart rate below 50 bpm
  - Pauses >3 times the cycle length of the ventricular escape rhythm
  - Complex ventricular ectopy
  - Prolonged QT interval
  - Ventricular dysfunction, ventricular dilatation or significant mitral regurgitation

Conduction Disorders with 1:1 Atrioventricular Conduction

Permanent pacemaker implantation is indicated for any of the following:

- Individuals with syncope and bundle branch block and one of the following at electrophysiology study (EPS):
  - Baseline HV interval ≥70 ms
  - Second- or third-degree intra- or infra-Hisian block during incremental atrial pacing
- Alternating bundle branch block with or without symptoms
- HV interval ≥100 milliseconds noted at EPS, with or without symptoms

- Intra- or infra- Hisian block noted at EPS, with or without symptoms

Recurrent syncope

Permanent pacemaker implantation is indicated for individuals with recurrent syncope and any of the following:

- Spontaneous documented symptomatic asystolic pause >3 seconds due to sinus arrest or atrioventricular block (AVB)
- Spontaneous documented asymptomatic asystolic pause >6 seconds due to sinus arrest or AVB
- Cardioinhibitory carotid sinus syndrome as documented by one of the below:
  - Syncope caused by spontaneously occurring carotid sinus stimulation
  - Carotid sinus pressure that induces syncope and/or ventricular asystole of ≥3 seconds
- Syncope associated with asystole of ≥3 seconds during tilt testing
- Bundle branch block and one of the following at electrophysiology study (EPS):
  - Baseline HV interval ≥70 ms
  - Second- or third-degree intra- or infra-Hisian block during incremental atrial pacing
- Syncope after cardiac transplantation with or without documentation of bradyarrhythmia

Peri-procedural and post-operative indications

Permanent pacemaker implantation is indicated for any of the following:

- Prior to a planned catheter ablation of the atrioventricular (AV) junction for one of the following:
  - Rate control strategy for management of atrial fibrillation
  - Supraventricular tachycardia resulting in tachycardia induced cardiomyopathy that is not controlled with ablation or medical therapy
- Post Transcatheter Aortic Valve Implantation (TAVI) for any of the following:
  - Complete or high-degree atrioventricular block (AVB) that persists for 24 to 48 hours after TAVI
  - New-onset alternating bundle branch block after TAVI
  - Pre-existing right bundle branch block (RBBB) and new conduction abnormality onset during or after (TAVI) such as:
    - Transient high-degree AVB
    - PR prolongation
    - QRS axis change

- Sinus node dysfunction or AVB associated with symptoms or hemodynamic instability occurring after cardiac surgery that does not resolve within 5 days
- Post cardiac transplant for any of the following:
  - Relative bradycardia that is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery
  - Syncope with or without documentation of bradyarrhythmia

Neuromuscular diseases known to involve the heart

Permanent pacemaker implantation may be considered for progressive neuromuscular diseases known to involve the heart with any degree of atrioventricular (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

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

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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)

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CPT® codes addressed

CPT® 33274, CPT® 0795T, CPT® 0796T, CPT® 0797T, CPT® 0801T,CPT® 0802T, CPT® 0803T, CPT® 0823T, CPT® 0824T, CPT® 0825T

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

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