CIGNA MEDICAL COVERAGE POLICIES

Pacemaker Guidelines

Effective Date: March 1, 2025

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 (CRID-1)

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Terms used in this guideline

Abbreviations

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

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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
TAVI	Transcatheter aortic valve implantation
TAVR	Transcatheter aortic valve replacement
VF	Ventricular fibrillation
VT	Ventricular tachycardia

Definitions

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 bed-bound 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.

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.
TAVR (TAVI)	A minimally invasive procedure to treat aortic valve stenosis

General Guidelines (CRID-1.0)

General requirements

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 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.
- Requests for a device when a same or similar device has already been placed is not supported without clear documentation that fulfills guideline criteria.

Procedures should be requested after initial consultation and physician treatment planning that includes full counseling of the individual with shared decision-making.

Procedure codes

Procedure description	CPT®
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	33206

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Procedure description	CPT®
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 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

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 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 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, 0801T, 0802T, 0803T, 0825T) 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

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Permanent Pacemaker Implantation (CRID-7)

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Codes included

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

Indications for Permanent Pacemaker (CRID-7)

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) is a consequence of essential medical 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)

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- 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
  - 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 related to bradycardia such as syncope, pre-syncope, heart failure symptoms, exertional fatigue, or impaired exercise tolerance
  - 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

Permanent Pacemaker Implantation - Non-indications (CRID-9)

- Permanent pacemaker implantation is **not** indicated in any of the following settings:
  - Sinus node dysfunction when there is documentation of any of the following
    - Individual is asymptomatic
    - The symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia

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    - Sinus node dysfunction is due to nonessential drug therapy
- Fascicular block without AV block or without symptoms concerning for AV block
- Incidentally noted hypersensitive cardioinhibitory response to carotid sinus stimulation when the individual remains asymptomatic or has vague symptoms
- Asymptomatic first-degree AV block
- Asymptomatic type-1 second-degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian
- Asymptomatic transient AV block in the absence of intraventricular conduction defects or in isolated single fascicular block
- Situational vasovagal syncope when avoidance behavior is effectively preventing syncopal episodes
- Prior to Transcatheter Aortic Valve Replacement (TAVR) as a prophylactic measure in individuals with right bundle branch block (RBBB) when there is no indication for permanent pacing
- For the purpose of cardiac contractility modulation

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Leadless Pacemaker (CRID-11.1)

CID.PM.111.A
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Codes included

Description	CPT®
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 (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)	0795T
Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (e.g., interrogation or programming), when performed	0823T

Indications

Leadless right ventricular pacemaker (CRID-11.1.1)

Indications for permanent right ventricular leadless pacemaker (CPT® 33274) implant - **all** of the following must be met:

- Meets **one** of the following indications for leadless right ventricular pacemaker:
  - Symptomatic paroxysmal or permanent high-grade AV block in the presence of Atrial Fibrillation (AF)
  - Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
  - Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber

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pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- The following contraindications for leadless pacemaker are **not** present:
  - An implanted inferior vena cava filter
  - A mechanical tricuspid valve

Leadless dual chamber pacemaker system (CRID-11.1.2)

Indications for permanent dual chamber leadless pacemaker implant (CPT® 0795T) - **all** of the following must be met:
- Meets one of the following indications for leadless dual chamber pacemaker:
  - Sick sinus syndrome
  - Chronic, symptomatic second- and third-degree AV block
  - Recurrent Adams-Stokes syndrome
  - Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out
- The following contraindications for leadless pacemaker are **not** present:
  - An implanted inferior vena cava filter
  - A mechanical tricuspid valve

Leadless right atrial pacemaker (CRID-11.1.3)

Indications for permanent leadless right atrial pacemaker implant (CPT® 0823T) - **all** of the following must be met:
- Meets the following indication for leadless right atrial pacemaker:
  - Sinus node dysfunction with normal AV and intraventricular conduction systems
- The following contraindications for leadless pacemaker are not present:
  - An implanted inferior vena cava filter
  - A mechanical tricuspid valve

General information

Right ventricular leadless pacemaker

The permanent right ventricular leadless pacemakers (CPT® 33274) consists of a single leadless device implanted directly into the right ventricle. The Medtronic Micra™ VR and Abbott Aveir™ VR right ventricular leadless pacemakers are capable only of VVI and VVIR pacing. The Medtronic Micra™ AV right ventricular leadless

pacemaker is also capable of VDD pacing. The right ventricular leadless pacemakers do not have capability for atrial pacing. The estimated battery life is about 10 years

Dual chamber leadless pacemaker

In contrast to the right ventricular leadless pacemakers referred to above, the dual chamber leadless pacemaker (i.e., Abbott Aveir™ DR leadless pacemaker system) has dual-chamber sensing and pacing functionality. The Abbott Aveir™ DR leadless pacemaker system consists of two separate components: one implanted in the right atrium and the other in the right ventricle.

References

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