MEDICAL POLICY

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Medical Policy Title	**Pacemakers and Cardiac Resynchronization Therapy (CRT) Devices**
Policy Number	**7.01.58**
Current Effective Date	**June 15, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Permanent Pacemakers

I. Permanent Pacemaker implantation is considered **medically appropriate** for **ANY** of the following indications:

A. Sinus node dysfunction:

1. Symptomatic non-reversible sinus node dysfunction as evidenced by **BOTH** of the following:

a. Documented sinus node dysfunction including **ONE** (1) of the below:

i. Sinus bradycardia at rate less than 50 beats per minute; **or**

ii. Sinus pauses greater than three (3) seconds; **and**

b. Symptoms attributable to non-reversible sinus node dysfunction including **ONE** (1) of the below:

i. Syncope or pre-syncope;

ii. Heart failure symptoms; **or**

iii. Exertional fatigue and impaired exercise tolerance;

2. Sinus bradycardia at rate less than 40 beats per minute and symptoms possibly related to bradycardia;

3. Symptomatic sinus bradycardia (as defined above) is a consequence of essential medical management and continued treatment is clinically necessary;

4. 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 [AF]);

5. Symptomatic chronotropic incompetence defined as limitations in activity due to the inability of the heart to increase its rate during exercise to achieve 80% of maximum predicted heart rate (220-age); **or**

B. Atrioventricular block (AVB):
   1. AVB including **ONE** of the following with or without symptoms:
      a. Second-degree Mobitz type II;
      b. High-grade (greater or equal to two (2) consecutive P waves at a constant physiologic rate that do not conduct to the ventricles); **or**
      c. Third-degree (complete heart block);
   2. Any degree of AVB with **ONE (1)** of the following symptoms that are clearly attributable to the AVB:
      a. Syncope or pre-syncope;
      b. Heart failure symptoms; **or**
      c. Exertional fatigue and impaired exercise tolerance;
   3. 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 AVB;
   4. Marked first-degree AVB (PR interval >0.3 seconds) or second-degree AVB with symptoms similar to those of pacemaker syndrome;
   5. Symptomatic AVB because of guideline directed management and continued treatment is clinically necessary;
   6. Persistent or permanent AF and symptomatic bradycardia including **EITHER** of the following:
      a. Rate less than 50 bpm; **or**
      b. Regular QRS intervals indicating complete AVB;
   7. Second-degree AVB with **any** of the following documented:
      a. A pause of greater or equal to five (5) seconds during waking in the presence of AF, with or without symptoms;
      b. Periods of asystole greater or equal to 3.0 seconds in the presence of sinus rhythm, with or without symptoms;
      c. Second-degree AVB noted to be located at intra-His or infra-His levels at electrophysiology study (EPS), with or without symptoms; **or**
      d. Any AVB indication listed above occurring after acute myocardial infarction that does not resolve within five (5) days;
   8. Congenital complete or high-degree AVB in the presence of **ANY** of the following;
      a. Symptoms related to bradycardia such as syncope, presyncope, heart failure

symptoms, exertional fatigue, or impaired exercise intolerance;

b. Wide QRS escape rhythm;

c. Mean daytime heart rate below 50 bpm;

d. Pauses greater than three (3) times the cycle length of the ventricular escape rhythm;

e. Complex ventricular ectopy;

f. Prolonged QT interval; **or**

g. Ventricular dysfunction, dilation or significant mitral regurgitation; **or**

C. Conduction disorders with 1:1 atrioventricular conduction:

1. Individuals with syncope and bundle branch block (BBB) and **ONE** (1) of the following at electrophysiology study (EPS):

a. Baseline His-Ventricular (HV) interval greater than or equal to 70 milliseconds (ms) (see policy guidelines); **or**

b. Second- or third-degree intra-Hisian or infra-Hisian block during incremental atrial pacing;

2. Alternating BBB with or without symptoms;

3. HV interval greater or equal to 100 ms noted at EPS, with or without symptoms;

4. Intra-Hisian or infra-Hisian block noted at EPS, with or without symptoms; **or**

D. Recurrent syncope related to **ANY** of the following:

1. Spontaneous documented symptomatic asystolic pause greater than 3 seconds due to sinus arrest or atrioventricular AVB;

2. Spontaneous documented asymptomatic asystolic pause greater than 6 seconds due to sinus arrest or AVB;

3. Cardioinhibitory carotid sinus syndrome as documented by **ONE** (1) of the below:

a. Syncope caused by spontaneously occurring carotid sinus stimulation; **or**

b. Carotid sinus pressure that induces syncope and/or ventricular asystole of greater than or equal to three (3) seconds;

4. Syncope associated with asystole of greater than or equal to three (3) seconds during tilt testing;

5. Bundle branch block and **ONE** (1) of the following at electrophysiology study (EPS):

a. Baseline HV interval greater than or equal to 70 ms; **or**

b. Second- or third-degree intra-Hisian or infra-Hisian block during incremental atrial

pacing;

6. Syncope after cardiac transplantation with or without documentation of bradyarrhythmia;
7. Recurrent Adams-Stokes syndrome; **or**

E. Peri-procedural and post-operative indications:

1. Prior to a planned catheter ablation of the atrioventricular (AV) junction for **ONE** (1) of the following:
   a. Rate control strategy for management of AF; **or**
   b. Supraventricular tachycardia resulting in tachycardia induced cardiomyopathy that is not controlled with ablation or medical therapy;
2. Post Transcatheter Aortic Valve Implantation (TAVI) for **ANY** of the following:
   a. Complete or high-degree atrioventricular block (AVB) that persists for 24 to 48 hours after TAVI;
   b. New onset alternating bundle branch block after TAVI; **or**
   c. Pre-existing right bundle branch block (RBBB) and new conduction abnormality onset during or after a TAVI such as:
      i. Transient high-degree AVB;
      ii. PR prolongation;
      iii. QRS axis change;
3. Sinus node dysfunction or AVB associated with symptoms or hemodynamic instability occurring after cardiac surgery that does not resolve within five (5) days;
4. Post cardiac transplant for **EITHER** of the following:
   a. Relative bradycardia that is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery; **or**
   b. Syncope with or without documentation of bradyarrhythmia; **or**

F. Neuromuscular diseases known to involve the heart:

1. 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:
   a. Myotonic muscular dystrophy;
   b. Kearns-Sayre syndrome;
   c. Erb dystrophy (limb-girdle muscular dystrophy); **or**

d. Peroneal muscular atrophy.

II. Upgrade of a single-chamber ventricular pacemaker (VVI) to a dual-chamber pacemaker (DDD) is **medically appropriate** for **ANY** of the following indications:

A. Sinus node dysfunction, where atrial pacing is required to maintain chronotropic competence;

B. Atrioventricular (AV) conduction abnormalities, including first-degree, second-degree (Mobitz I or II), high-grade AV block, or complete heart block, where synchronized atrioventricular pacing is anticipated to improve hemodynamic performance;

C. Symptoms consistent with pacemaker syndrome (fatigue, hypotension, or syncope resulting from the loss of AV synchrony).

III. Permanent pacemaker implantation is considered **not medically appropriate** for **ANY** of the following indications:

A. Sinus node dysfunction when there is documentation of **ANY** of the following:

1. Individual is asymptomatic;

2. The symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia; **or**

3. Sinus node dysfunction is due to nonessential drug therapy;

B. Fascicular block without AV block or without symptoms concerning for AV block;

C. Incidentally noted hypersensitive cardioinhibitory response to carotid sinus stimulation when the individual remains asymptomatic or has vague symptoms;

D. Asymptomatic First-degree AV block;

E. 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;

F. Asymptomatic transient AV block in the absence of intraventricular conduction defects or in isolated single fascicular block;

G. Situational vasovagal syncope when avoidance behavior is effectively preventing syncopal episodes;

H. Prior to TAVR as a prophylactic measure in individuals with RBBB when there is no indication for permanent pacing;

I. For the purpose of cardiac contractility modulation (CCM).

IV. Upgrade of a VVI to a DDD is **not medically necessary** for the indication of persistent AF when it is not part of a planned rhythm control strategy.

V. Biventricular pacing is considered **investigational** for patients who do not meet any of the indications identified above.

Leadless Right Ventricular Pacemakers

VI. Permanent right ventricular leadless pacemaker implant is considered **medically appropriate** when **BOTH** of the following criteria are met:

A. Meets **ANY** of the following indications:

1. Symptomatic paroxysmal or permanent high-grade AV block in the presence of AF;
2. 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; **or**
3. Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy;

AND

B. The following contraindications for leadless pacemaker are **NOT** present:

1. An implanted inferior vena cava filter;
2. A mechanical tricuspid valve.

Leadless Dual Chamber Pacemaker System

VII. Permanent dual chamber leadless pacemaker (CPT 0795T) implants are considered **medically appropriate** when **ALL** of the following criteria are met:

A. Specific criteria from Policy Statement I must be met for the following indications: (Indications are linked to associated criteria)

1. Sinus node dysfunction;
2. AV block;
3. Conduction disorders with 1:1 atrioventricular conduction;
4. Recurrent syncope;
5. Peri-procedural and post-operative indications; **or**
6. Neuromuscular diseases;

AND

B. The following contraindications for leadless pacemaker are **NOT** present:

1. An implanted inferior vena cava filter;
2. A mechanical tricuspid valve.

Leadless Right Atrial Pacemaker

VIII. Permanent leadless right atrial pacemaker (CPT 0823T) implants are considered **medically appropriate** when **BOTH** of the following criteria are met:

A. Symptomatic sinus node dysfunction (dizziness, syncope, shortness of breath) with normal AV and intraventricular conduction systems;

AND

B. The following contraindications for leadless pacemaker are **NOT** present:

1. An implanted inferior vena cava filter;
2. A mechanical tricuspid valve.

Cardiac Resynchronization Therapy (CRT)-D implantation

IX. CRT-D implantation is considered **medically appropriate** for the treatment of individuals who meet **ANY** of the following indications:

A. Ischemic or nonischemic dilated cardiomyopathy when left ventricular (LV) ejection fraction less than or equal to 35% despite three (3) months of optimal medical therapy (OMT) when **any** of the following indication specific criteria are met:

1. Sinus rhythm with Left bundle branch block (LBBB) with **both** of the following:
   a. New York Heart Association (NYHA) Functional Class II, III, or ambulatory class IV; **and**
   b. QRS greater than or equal to 120 msec to 149 msec; **or**
2. Sinus rhythm **with** LBBB and **both** of the following criteria are met:
   a. NYHA Functional Class I, II, III, or ambulatory class IV; **and**
   b. QRS greater than or equal to 150 msec; **or**
3. Sinus rhythm **with non**-LBBB with **both** of the following:
   a. NYHA class III, or ambulatory class IV; **and**
   b. QRS duration greater or equal to 150 msec; **or**
4. Atrial fibrillation (AF), persistent or permanent with **both** of the following:
   a. QRS duration greater or equal to 150 msec; **and**
   b. LBBB; **or**

B. Individuals that are currently or anticipated to need RV pacing with an indication for an ICD and **all** of the following criteria:

1. NYHA Functional Class I, II, III, or ambulatory IV.
2. Current or anticipated RV pacing over 40%; **and**

3. LVEF less than or equal to 35% after greater than or equal to three (3) months of OMT;

X. CRT-P (Pacing) is considered **medically appropriate** when an individual meets **BOTH** of the following criteria:

A. Requirements of CRT-D have been met;

AND

B. The individual in consultation with the providing physician declines the ICD function.

XI. Upgrade to CRT-D is **medically necessary** in individuals who have an implanted non-CRT-D ICD when **EITHER** of the following conditions are documented:

A. LVEF greater than or equal to 50% prior to ICD implant and **both** of the following are documented:

1. RV pacing burden greater than or equal to 40%; **and**
2. **One** of the following changes has occurred after implantation of non-CRT ICD:
   a. Decline in LVEF greater than or equal to 10%; **or**
   b. New or worsening heart failure symptoms (NYHA Class II or III); **or**

B. LVEF less than or equal to 35% after greater than or equal to three (3) months of OMT and **both** of the following are documented:

1. New or worsening symptomatic heart failure (NYHA Class II, III, or ambulatory class IV) following implantation of a non-CRT pacemaker or ICD; **and**
2. Ventricular pacing greater than or equal to 40%.

XII. CRT-D or CRT-P implantation is considered **not medically appropriate** for **EITHER** of the following indications (Unless a separate indication for permanent pacemaker implantation exists, thus preventing a likely repeat procedure for an upgraded device in the near future):

A. Individuals who have had a myocardial infarction within the past 40 days;

B. Coronary revascularization within the past 90 days.

XIII. CRT-D implantation is considered **not medically appropriate** in the setting of a reversible cardiomyopathy such as: toxic, metabolic, or tachycardia induced cardiomyopathy. Once the reversible aberration is corrected, clinical reassessment is indicated.

<u>Cardiac Resynchronization Therapy (CRT)-P</u>

XIV. CRT-P implantation is considered **medically appropriate** for **ANY** of the following:

A. High grade AV block and **ALL** of the following:

1. Initial CRT-P implantation;
2. LV ejection fraction less than 50%;

3. NYHA Class I, II or III congestive heart failure; **and**
4. High grade AV block, including AV nodal ablation, requiring more than 40% ventricular pacing (CRT)-P;

B. Pacing induced cardiomyopathy requesting an upgrade from non-CRT pacemaker to CRT-P with **ALL** of the following:

1. LVEF greater than 50% prior to implantation or non-CRT pacemaker;
2. Right ventricular pacing burden greater or equal to 40%; **and**
3. **One** (1) of the following occurring after implantation of non-CRT pacemaker:
   a. Decline in LVEF greater or equal to 10%; **or**
   b. New or worsening heart failure symptoms NYHA Class II or III.

Indications for Conduction System Pacing

XV. His bundle pacing or LBB area pacing (CPT 33207 or 33208) is considered **medically appropriate** when **ALL** of the following are met:

A. Indications for CRT-P (Policy Statement XIV) are met and **one** (1) of the following are met:

1. LV lead placement was attempted and was unsuccessful or suboptimal; **or**
2. His bundle pacing or LBB area pacing is planned in place of biventricular pacing.

Wireless Cardiac Resynchronization

XVI. Permanent LV leadless pacemakers (CPT 0515T) that are directly implanted in the LV for synchronization with right ventricle (RV) leads in the setting of cardiac resynchronization is considered **investigational**.

Intrathoracic Fluid Monitoring

XVII. Intrathoracic fluid monitoring sensors are considered **investigational** as a component of a biventricular pacemaker.

RELATED POLICIE(S)

Corporate Medical Policy

7.01.06 Implantable Cardiac Defibrillators (ICD)

7.01.91 Heart Failure Management Devices

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Optimal medical therapy for heart failure should include a beta-blocker and **one** of the following:

A. ACE inhibitors;

B. Angiotensin II receptor blocker; or

C. Angiotensin receptor-neprilysin inhibitor.

II. The His-Ventricular (HV) interval is a measure of the conduction time from the His bundle to the ventricular myocardium.

III. The New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994) are defined as follows:

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea.
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.
- Class IV: Class IV heart failure with no active acute coronary syndrome; no inotropes; and on guideline-directed medical therapy (GDMT) defined as initial medical therapy with angiotensin-converting enzyme inhibitors (ACE) or angiotensin-receptor blockers (ARB), beta-blockers (BB), and mineralocorticoid receptor antagonists (MRA) titrating to maximally tolerated doses for patients with heart failure with reduced ejection fraction (HFrEF).

DESCRIPTION

Approximately 30 percent of people with chronic heart failure have intraventricular conduction disorders resulting in a discoordinated contraction pattern and a wide QRS interval on the electrocardiogram (EKG). Studies suggest that this intraventricular conduction delay is associated with increased morbidity and mortality. Prolonged QRS duration in these patients contributes to abnormal septal wall motion, reduced cardiac contractility, decreased diastolic filling time and extended mitral valve regurgitation. Biventricular pacing, or cardiac resynchronization therapy (CRT), along with optimal medical therapy, has demonstrated improved hemodynamic status in some patients with chronic heart failure.

CRT therapy is treatment is used to help the heartbeat with the correct rhythm, it uses pacemakers to restore the normal timing pattern of the heartbeat. The CRT pacemakers (CRT-P) coordinates how timing of the upper heart chambers and the lower heart chambers and works on the timing between the left and the right sides of the heart. CRT with pacemaker and an implantable cardiac defibrillator (ICD) (CRT-D) this device can detect dangerous heart rhythms and deliver a stronger shock than a pacemaker, to reset the heartbeat.

InSync Sentry system is a combined biventricular pacemaker/AICD is additionally equipped to monitor intrathoracic fluid levels using bioimpedance technology, referred to as Optivol Fluid Status

monitoring. Bioimpedance measures are performed using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted pacemaker device; changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. Adding intrathoracic fluid status monitoring has been proposed as a more sensitive monitoring technique, because a change in fluid status may be an early indicator of impending heart failure, permitting early intervention and, it is hoped, resulting in a decreased rate of hospitalization. At this time there is insufficient evidence to evaluate the benefit of bioimpedance monitoring on the clinical management of patients with heart failure. Medtronic, the manufacturer of the OptiVol Fluid Status Monitoring feature of the InSync Sentry system, has announced several ongoing clinical trials of the device.

Wireless LV Pacemaker

The wireless Stimulation Endocardial (WiSE) for Cardiac Resynchronization (CRT) system delivers ultrasonic energy to a LV endocardial receiver electrode to achieve biventricular pacing. A percutaneously delivered LV endocardial receiver electrode (instead of a lead) and powered wirelessly by a subcutaneous ultrasound pulse generator. The transmitter placed subcutaneously sends ultrasound to an electrode in the left ventricle, which converts the ultrasound waves into an electrical stimulation potential. The transmitter is connected to the battery via a cable that serves as a source of energy. With a very short delay (3–10ms), the transmitter can send a preprogrammed ultrasonic pulse acoustically to the electrode. The electrode converts the ultrasonic energy into electrical energy, which is used to activate the left ventricle. Stimulation can be simultaneous and biventricular due to the endocardial stimulation site. The WiSE CRT System is designed to improve the heart's pumping ability by synchronizing the left and right ventricles to distribute blood to the lungs and body more effectively.

Right Ventricular Leadless Pacemaker

The permanent right ventricular leadless pacemakers (CPT 33274) consist 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 (i.e., Abbott Aveir DR Leadless Pacemaker System)

In contrast to the right ventricular leadless pacemakers, dual chamber leadless pacemakers have 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.

SUPPORTIVE LITERATURE

Sudesh et al (2024) conducted a patient-level meta-analysis of seven randomized clinical trials: MIRACLE, MIRACLE-ICD (Multi-center InSync ICD Randomized Clinical Evaluation), MIRACLE-ICD II, COMPANION, REVERSE, MADIT-CRT, and RAFT (Resynchronization-Defibrillation for Ambulatory

Heart Failure). The study analyzed data from 6,252 patients using Bayesian Hierarchical Weibull survival regression and linear regression to examine the impact of cardiomyopathy etiology on outcomes and echocardiographic changes. Among the participants, 59% had ischemic cardiomyopathy (ICM), and 60% received cardiac resynchronization therapy (CRT). CRT significantly prolonged time to heart failure hospitalization or all-cause death (HR: 0.67; 95% CrI: 0.56–0.82) and reduced mortality (HR: 0.71; 95% CrI: 0.55–0.93), with no difference by etiology. Echocardiographic improvements in left ventricular function and dimensions were greater in non-ischemic cardiomyopathy (NICM) patients. Overall, CRT improved survival and reduced hospitalizations regardless of etiology, though NICM patients experienced more pronounced structural benefits, highlighting the need for better patient selection strategies.

Cang et al (2022) conducted A meta-analysis, five studies involving 175 Heart failure patients for WiSE CRT were included, and patients were followed for six months. The implanted success rate ranged from 76.5 to 100%. WiSE CRT resulted in significantly narrower QRSd [mean difference (MD):−38.21ms, 95% confidence interval (CI): −44.36 to −32.07, $p < 0.001$], improved left ventricular ejection fraction (MD: 6.07%, 95% CI: 4.43 to 7.71, $I2 = 0\%$, $p < 0.001$), reduced left ventricular end-systolic volume (MD: −23.47ml, 95% CI: −37.18 to −9.13, $p < 0.001$), and reduced left ventricular end-diastolic volume (MD: −24.02ml, 95% CI:−37.01 to −11.03, $p = 0.02$). The evidence from current studies suggests that leadless endocardial LV pacing resynchronization is effective for heart failure patients who have failed conventional CRT or needed a device upgrade, more research is needed to determine its use for rescue therapy.

Okabe et al (2022) conducted a prospective study to present short-term outcomes with WiSE-CRT system in centers with no prior implanting experience. The data was prospectively collected from 19 centers where WiSE-CRT systems were implanted during the roll-in phase of the SOLVE-CRT. The SOLVE-CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients) study is an international, multicenter prospective randomized trial of the WiSE-CRT system evaluating its efficacy and safety in CRT non-responders and CRT-eligible patients who were previously untreated. Patients were followed at 1, 3, and 6 months, including transthoracic echo (TTE) at 6 months. WiSE-CRT was successfully implanted in all 31 attempted cases, and 30 patients completed the 6-month follow-up. Fourteen (46.7%) patients demonstrated greater or equal to NYHA class improvement. Transthoracic electrocardiogram data were available in 29 patients. The study demonstrated a high success rate of LV endocardial electrode placement in centers with no prior implanting experience. Favorable clinical responses in heart failure symptoms and significant LV reverse remodeling were noted.

PROFESSIONAL GUIDELINE(S)

Professional Society	Title of Guideline	Year
American College of Cardiology (ACC)/ American Heart Association	Appropriate Use Criteria for Implantable Cardioverter Defibrillators, Cardiac	2025

(AHA)/ASE/Heart Failure Society of America (HFSA)/Heart Rhythm Society (HRS)/Society of Cardiovascular Angiography & Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society of Cardiovascular Magnetic Resonance (SCMR)	Resynchronization Therapy, and Pacing	
HRS/ Asia Pacific Heart Rhythm Society (APHRS)/ Latin American Heart Rhythm Society (LAHRS)	Guideline on cardiac physiologic pacing for the avoidance and mitigation of heart failure	2023
ACC/AHA/ACCP/HRS	Guidelines for the Diagnosis and Management of Atrial Fibrillation	2023
AHA/ACC/ HFSA	Guideline for the Management of Heart Failure	2022
ACC/AHA/HRS	Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay	2018
AHA/ACC/HRS	Guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death	2017
ACC Foundation (ACCF)/AHA/HRS	Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities	2012

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates cardiac devices as medical devices. All cardiac devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 23]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 23]

In 2025, the Concerto/InSync Sentry/InSync Maximo implantable cardiovascular defibrillators with cardiac resynchronization systems received FDA approval through the supplemental PMA process.

In 2019, the U.S. FDA granted Breakthrough Device Designation for the WiSE (Wireless Stimulation Endocardially) CRT System (EBR Systems, Inc) for the treatment of heart failure. The WiSE-CRT has

European CE approval and continues to be studied in clinical trials to assess its safety and efficacy in support of U.S. FDA approval.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0515T (E/I)	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])
0516T (E/I)	electrode only
0517T (E/I)	both components of pulse generator (battery and transmitter) only
0518T (E/I)	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; battery component only
0519T (E/I)	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; both components (battery and transmitter)
0520T (E/I)	battery component only
0521T (E/I)	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing
0522T (E/I)	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing
0695T (E/I)	Body surface–activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of implant or replacement
0696T (E/I)	at time of follow-up interrogation or programming device evaluation

Code	Description
0795T	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)
0796T	right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	dual-chamber system (i.e., right atrial and right ventricular pacemaker components)
0802T	right atrial pacemaker component
0803T	right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0823T	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
0824T	Transcatheter removal 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), when performed
0825T	Transcatheter removal and replacement 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
33202	Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
33203	endoscopic approach (e.g., thoracoscopy, pericardioscopy)
33206	Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	ventricular
33208	atrial and ventricular

Code	Description
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)
33212	Insertion of pacemaker pulse generator only; with existing single lead
33213	with existing dual leads
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new generator)
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220	Repair of two transvenous electrodes for permanent pacemaker or implantable defibrillator
33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33222	Relocation of skin pocket for pacemaker
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound,

Code	Description
	ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed
93281	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system

HCPCS Codes

Code	Description
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7540	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system, with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)

ICD10 Codes

Code	Description
I09.81	Rheumatic heart failure
I11.0-I11.9	Hypertensive heart disease (code range)
I44-I44.2	Atrioventricular and left bundle branch block (code range)
I44.3-I44.5	Other and unspecified atrioventricular block (code range)
I44.6-I44.7	Other and unspecified fascicular block (code range)
I49.9	Cardiac arrhythmia, unspecified
I49.5	Sick sinus syndrome
I50.1-I50.9	Heart failure (code range)
Q24.6	Congenital heart block

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cardiac resynchronization therapy for heart failure is not addressed in National or Regional Medicare coverage determinations or policies.

Leadless Pacemakers (NCD 20.8.4) [accessed 2025 Dec 30].

Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (Billing and Coding A54909) [accessed 2025 Dec 30].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

11/21/02, 10/15/03, 08/19/04, 04/21/05, 01/19/06, 11/16/06, 09/20/07, 10/23/08, 09/17/09, 04/22/10, 06/16/11, 06/21/12, 06/20/13, 08/21/14, 07/16/15, 07/21/16, 07/20/17, 08/16/18, 08/15/19, 07/16/20, 08/19/21, 08/18/22, 08/17/23, 04/18/24, 01/23/25, 02/19/26

Date	Summary of Changes
02/19/26	• Annual review. Cardiac Contractility Modulation (CCM) devices were moved to policy 7.01.06 Heart Failure Devices. New indications to medically necessary statement for upgrade to a CRT-D. New medically appropriate indications for CRT-D. Added medically necessary statement for upgrade of a single-chamber ventricular pacemaker (VVI) to a dual-chamber pacemaker (DDD). Added not medically necessary statement for upgrade of a VVI to a DDD. Added recurrent Adam-Stokes syndrome to indications for pacemaker under recurrent syncope. Code deletions: 0408T, 0409T, 0915T, 0916Tand 0923T.
07/30/25	• Code edits, added 0408T and 0409T, policy intent unchanged.
01/23/25	• Annual review. Title change. Code edits, added 0915T, 0916T, and 0923T. Policy statement added for Cardiac Contractility Modulation Devices (CCM) as investigational.
01/01/25	• Summary of changes tracking implemented.
11/21/02	• Original effective date