MEDICAL POLICY

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Medical Policy Title	**Pacemakers, Cardiac Resynchronization Therapy (CRT) Devices and Cardiac Contractility Modulation (CCM) Devices**
Policy Number	**7.01.58**
Current Effective Date	May 15, 2025
Next Review Date	January 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (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 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 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 due to the inability to achieve 80% of maximum predicted heart rate (220-age).

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; 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 **ONE (1)** of the following:
   a. Rate less than 50 bpm; or
   b. Regular QRS intervals indicating complete AVB;
7. Second-degree AVB with a documented pause of greater or equal to five (5) seconds during waking in the presence of AF, with or without symptoms;
8. Second degree AVB with documented periods of asystole greater or equal to 3.0 seconds in the presence of sinus rhythm, with or without symptoms;
9. Second-degree AVB noted to be located at intra- or infra-His levels at electrophysiology study (EPS), with or without symptoms;
10. Any AVB indication listed above occurring after acute myocardial infarction that does not resolve within five (5) days;
11. Congenital complete or high-degree AVB in the presence of **ANY** of the following;
    a. Symptomatic- 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;

g. Ventricular dysfunction, dilation or significant mitral regurgitation.

C. Conduction disorders with 1:1 atrioventricular conduction:

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

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

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

2. Alternating bundle branch block with or without symptoms;

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

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

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

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

2. Spontaneous documented asymptomatic asystolic pause >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;

b. Carotid sinus pressure that induces syncope and/or ventricular asystole of ≥3 seconds;

4. Syncope associated with asystole of ≥3 seconds during tilt testing;

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

a. Baseline HV interval ≥70 ms;

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

6. Syncope after cardiac transplantation with or without documentation of bradyarrhythmia.

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;

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;

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 **ANY** of the following:

a. Relative bradycardia that is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery;

b. Syncope with or without documentation of bradyarrhythmia.

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);

d. Peroneal muscular atrophy.

II. 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;

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.

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

Leadless Right Ventricular Pacemakers

IV. Permanent right ventricular leadless pacemaker (CPT 33274) implants are considered **medically appropriate** when **ALL** of the following criteria are met:

A. Meets **ONE** (1) 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;
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;

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

V. Permanent dual chamber leadless pacemaker (CPT 0795T) implants are considered **medically appropriate** when **ALL** of the following criteria are met:
   A. Meets **ONE** (1) of the following indications:
      1. Sick sinus syndrome;
      2. Chronic, symptomatic second- and third-degree AV block;
      3. Recurrent Adams-Stokes syndrome;
      4. Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out;
   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

VI. Permanent leadless right atrial pacemaker (CPT 0823T) implants are considered **medically appropriate** when **ALL** of the following criteria are met:
   A. Sinus node dysfunction 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

VII. CRT-D implantation is considered **medically appropriate** for **ANY** of the following indications:
   A. Ischemic or nonischemic dilated cardiomyopathy with **either** of the following indications:
      1. Sinus rhythm with LBBB and **ALL** of the following criteria are met:
         a. Left ventricular (LV) ejection fraction less than or equal to 35% despite greater than or equal to 3 months of optimal medical therapy (OMT);
         b. Left bundle branch block (LBBB) with QRS greater than or equal to 120 msec;
         c. Symptomatic heart failure heart failure New York Heart Association (NYHA) functional class II, III, or ambulatory class IV;
      2. Sinus rhythm with non-LBBB and **ALL** of the following criteria are met:
         a. LV ejection fraction less than or equal to 35% despite greater than or equal to 3 months of OMT;

b. Non-LBBB pattern with QRS duration greater or equal to 150 msec;

c. Symptomatic heart failure NYHA class III, or ambulatory class IV;

B. Atrial Fibrillation and NYHA class II, III, or IV Congestive heart failure and **ALL** of the following criteria are met:

1. Meets **ONE** of the following CRT criteria:

a. LBBB with a QRS duration ≥120 ms and symptomatic heart failure NYHA functional class II, III, or ambulatory class IV;

b. Non-LBBB pattern with a QRS duration greater than or equal to 150 and symptomatic heart failure NYHA class III or ambulatory class IV;

2. Non-pharmacologic or pharmacologic rate control will allow near 100% biventricular pacing with CRT;

C. Dilated cardiomyopathy with AF requiring AV junction ablation for rate control and **ALL** of the following criteria are met:

1. LV ejection fraction less than or equal to 35% despite greater than or equal to 3 months of OMT;

2. Uncontrolled heart rate requiring AV junction ablation;

D. Sinus rhythm or AF with dilated cardiomyopathy with high-grade AV block and **ALL** of the following:

1. LV ejection fraction less than or equal to 35% despite greater than or equal to 3 months of OMT;

2. High-grade AV block requiring pacing;

E. Upgrade to CRT-D for individuals when **ALL** of the following criteria are met:

1. LV ejection fraction greater or less than 35% despite greater than or equal to 3 months of OMT;

2. New or worsening symptomatic heart failure (NYHA functional class II, III, or ambulatory class IV) following implantation of a non-CRT pacemaker or implantable cardioverter-defibrillator (ICD);

3. Ventricular pacing greater than 40%.

VIII. CRT-P (Pacing) is considered **medically appropriate** when individual meets **ALL** of the following:

A. Requirements of CRT-D have been met;

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

IX. 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.

X. 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.

Cardiac Resynchronization Therapy (CRT)-P

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

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

1. LV ejection fraction less than 50%;
2. NYHA class I, II or III congestive heart failure;
3. High grade AV block, including AV nodal ablation, requiring more than 40% ventricular pacing (CRT)-P;

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

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

Indications for Conduction System Pacing

XII. His bundle pacing or left bundle branch area pacing (CPT 33207 or 33208) may be considered when **ALL** of the following are met:

A. indications for CRT-P are met and **one** (1) of the following are met:

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

Wireless Cardiac Resynchronization

XIII. 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

XIV. Intrathoracic fluid monitoring sensor is considered **investigational** as a component of a biventricular pacemaker.

Cardiac Contractility Modulation Devices

XV. Cardiac contractility modulation (CCM) (e.g., Optimizer Smart) and combined CCM with ICD devices (CCM-D) (e.g., Optimizer Integra CCM-D System) are considered **investigational**.

RELATED POLICIE(S)

Corporate Medical Policy

7.01.06 Implantable Cardiac Defibrillators (ICD)

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 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:

Functional Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

Functional Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

Functional Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.

Functional 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.

Ambulatory Functional 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.

Wireless LV Pacemaker

The wireless Stimulation Endocardially for Cardiac Resynchronization (WiSE-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.

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.

Cardiac Contractility Modulation Devices (CCM)

Cardiac contractility modulation devices deliver electrical signals during the ventricular absolute refractory period. This does not generate an action potential or mechanical contraction. It is proposed to enhance ventricular contractile strength and potential treatment option for individuals with symptomatic heart failure with reduced LV ejection fraction who are not candidates for CRT. CCM has previously been used along with a separate ICD. The combined CCM and ICD (CCM-D) combines CCM and ICD in one device.

SUPPORTIVE LITERATURE

Several randomized clinical trials have identified beneficial outcomes to support that the use of biventricular pacemakers in the treatment of heart failure improves both hemodynamic and clinical performance. The evidence in the peer-reviewed literature supports the use of CRT to alleviate symptoms of severe heart failure in patients with ventricular dyssynchrony, decreased cardiac function, and optimal drug therapy. The studies in general report improved cardiac function, exercise tolerance, and quality of life, as well as a decrease in heart failure-related hospitalizations and a decrease in mortality in patients responding to CRT.

A sub analysis of the MADIT-CRT trial data (Zareba, 2011) of patients with NYHA class I/II CHF demonstrated that, compared with non-LBBB patients (those with RBBB or nonspecific intraventricular conduction disturbances), patients with LBBB QRS morphology showed significant clinical benefit from CRT-D therapy, as measured by reduced risk of heart failure event or death and risk of ventricular tachycardia/fibrillation or death. Non-LBBB patients did not benefit clinically, despite a significant reduction in left ventricular volumes. These findings formed the basis for recent FDA approval of new broadened indications for CRT in mild or asymptomatic heart failure patients with LBBB. There is still a question as to whether CRT therapy should be used in non-LBBB patients, even when advanced heart failure is present, and which non-LBBB patients might still benefit clinically from CRT. Further research investigating the rationale, mechanisms, and clinical benefit is needed to determine whether CRT therapy should be pursued in non-LBBB patients.

The REVERSE trial enrolled a total of 610 patients, all of whom received a CRT device. Patients were randomized to CRT-ON or CRT-OFF for a period of 12 months, in double-blind fashion. The primary outcome was a composite measure that classified patients as improved, unchanged, or worse. There were no significant differences reported on this primary outcome. There was a decrease in hospitalizations for heart failure in the CRT-ON group (4.1%, 17/419) compared with the CRT-OFF group (7.9%, 15/191). Changes in functional status, as measured by the 6-minute walk, were similar between groups. Quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire, was also similar between groups.

The MIRACLE ICD study was the smallest of the three studies, enrolling 186 patients with class II CHF and an indication for an ICD in an unblinded fashion. Patients were randomized to ICD/CRT-ON versus ICD/CRT-OFF and followed for six months. There was no difference in the primary outcome of peak oxygen uptake between groups. There were also no differences reported between groups on the secondary outcomes of functional status as measured by the six-minute walk, QOL as measured

by the Minnesota Living with Heart Failure Questionnaire, and New York Heart Association CHF class.

All three randomized, controlled trials reported significant improvements in echocardiographic measures of left-ventricular (LV) pump function. LV ejection fraction improved more in the CRT group in each trial, with a range of improvement of 3.0–11.0%, compared with the control group. There were also substantial improvements in LV end-systolic and end-diastolic volumes (LVESV, LVEDV) in all three trials. All reported relatively large improvements in the LVESV and the LVEDV in favor of the CRT group. Complications in these trials were not uniformly reported; however, each trial contained some information on short- and long-term complications. Short-term complication rates ranged from 4–22%, with lead dislodgement and hematoma at the access site most common. Long-term complications were reported by two of the trials, with rates of 16% and 35%. The majority of these long-term complications were lead dislodgement.

Cang et al. (2022) conducted A meta-analysis, five studies involving 175 Heart failure patients for WiSE CRT were included, and patients were followed-up 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.

A prospective study by Okabe et al. (2022) was conducted 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 nonresponders 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.

Cardiac Contractility Modulation Devices (CCM)

A non-randomized study looked at the FIX-HF-5C2 (2-lead CCM system study) and FIX-HF-5C (3-lead system study) randomized control trials and tested the safety and effectiveness of a 2-lead CCM system compared with the 3-lead CCM system. Individuals that participated in the trail had NYHA III/IVa symptoms despite medical therapy, LVEF 25% to 45%, and not eligible for CRT. All participants received an Optimizer 2-lead implant. The primary end point was the estimated

difference in the change of peak VO_2 from baseline to 24 weeks between FIX-HF-5C2 subjects relative to control subjects from the FIX-HF-5C. Secondary endpoint was changes in the NYHA functional classification. The primary safety end point was the comparison of device related adverse events between the two studies participants. Sixty subjects, 88% male, 66±9 years old with left ventricular ejection fraction 34±6% were included. Baseline characteristics were similar between FIX-HF-5C and FIX-HF-5C2 subjects except that 15% of FIX-HF-5C2 subjects had permanent atrial fibrillation versus 0% in FIX-HF-5C. CCM delivery did not differ significantly between 2-and 3-lead systems (19 892±3472 versus 19 583±4998 CCM signals/day, CI of difference [−1228 to 1847]). The change of peak VO_2 from baseline to 24 weeks was 1.72mL/kg per minute greater in the 2-lead device group versus controls. 83.1% of 2-lead subjects compared with 42.7% of controls experienced ≥1 class NYHA improvement (P<0.001). There were decreased Optimizer-related adverse events with the 2-lead system compared with the 3-lead system (0% versus 8%; P=0.03). Overall, device-related adverse effects were less with the 2-lead system. The 2-lead system effectively delivers comparable amount of CCM signals as the 3-lead system that includes subjects with AF and is equally as safe and improves peak VO_2 and NYHA functional class. Limitations that need to be addressed is that the study is non-randomized, unblinded, with a small number of participants (Wiegn 2020).

PROFESSIONAL GUIDELINE(S)

Professional Society Guidelines referenced for this policy:

Professional Society	Title of Guideline	Year
Heart Rhythm Society (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
American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (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

In 2005, the InSync Sentry system received FDA approval through the supplemental PMA process. This 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.

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 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. The WiSE-CRT provides biventricular pacing by sensing right ventricular pacing output from a previously placed conventional device (i.e., pacemaker or defibrillator using uni- or biventricular leads) that subsequently transmits an ultrasound pulse to the wireless electrode inserted onto the left ventricle endocardium resulting in a left ventricular pacing pulse emission. 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.

Cardiac Contractility Modulation Devices (CCM)

In 2018 OPTIMIZER Smart System was FDA approved and is indicated to improve 6-minute hall walk distance, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25% to 45%.

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)	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only
0517T (E/I)	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; 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)	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; 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 (Use 0695T in conjunction with 33224, 33225, 33226)
0696T (E/I)	at time of follow-up interrogation or programming device evaluation (Use 0696T in conjunction with 93281, 93284, 93286, 93287, 93288, 93289)

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
0915T (E/I)	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator and dual transvenous electrodes/leads (pacing and defibrillation)
0916T (E/I)	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator only

Code	Description
0923T (E/I)	Removal and replacement of permanent cardiac contractility modulation-defibrillation pulse generator only (Effective 01/01/25)
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	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	atrial and ventricular
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

Code	Description
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, 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)

Code	Description
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	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)

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)

Based upon our review, cardiac resynchronization therapy for heart failure is not addressed in National or Regional Medicare coverage determinations or policies.

Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (Billing and Coding A54909) [accessed 2024 Nov 20].

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

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

Date	Summary of Changes
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