Cohere Medicare Advantage Policy - Cardiac Implantable Devices

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medicare Advantage Policy - Cardiac Implantable Devices
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Service: Cardiac Implantable Devices

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-6]

- National Coverage Determination (NCD). Cardiac pacemakers - single chamber and dual chamber permanent cardiac pacemakers (20.8.3)
- National Coverage Determination (NCD). Implantable automatic defibrillators (20.4)
    - National Coverage Analysis (NCA). Implantable automatic defibrillators (CAG-00157R4)
- National Coverage Determination (NCD). Cardiac pacemakers (20.8)
- Local Coverage Determination (LCD). Cardiac resynchronization therapy (L39080)
    - Billing and Coding: Cardiac resynchronization therapy (A58821)

Description

A range of devices may be implanted directly into the heart to moderate its rhythm, including single or dual-chamber pacemakers, implantable cardioverter-defibrillators (ICDs), or a cardiac resynchronization therapy (CRT) device with or without a defibrillator. These devices generally emit an electrical impulse when an abnormal, dangerous rhythm is detected in order to precipitate a more normal pattern. During the insertion procedure, the patient is sedated and a small incision is made to house the device, usually below the collarbone; subcutaneous ICDs are often placed along the chest wall. Wires - known as leads - are directed through the veins of the chest into the appropriate chamber(s) of the heart, where they contact the cardiac wall to deliver electrical impulses. Conversely, subcutaneous ICDs do not pass through the veins; rather, the leads run beneath the skin across the surface of the chest, where the defibrillator rests above the breastbone. Substernal - or

extravascular - ICDs lie below the sternum. Depending on the clinical status and comorbidities of the patient, the patient may require either single-site or multiple-site pacing, added defibrillator function, or CRT with (CRT-D) or without a defibrillator (CRT-P). CRT is also referred to as biventricular (BiV) pacing. Newer techniques for cardiac resynchronization therapy include conduction system pacing (CSP), which involves His bundle pacing (HBP or HBP-CRT) or left bundle branch (LBB) pacing (LBBP-CRT), also called left bundle branch area pacing (LBBAP). These techniques engage the intrinsic cardiac conduction system and may closely reproduce the native ventricular activation sequence.[7-14]

Medical Necessity Criteria

Indications

A **cardiac implantable device** is considered appropriate if **ANY** of the following is **TRUE**:

- The device is an **implantable single or dual-chamber pacemaker [A],** and **ANY** of the following is **TRUE**[1]:
  - Treatment of non-reversible, symptomatic bradycardia due to sinus node dysfunction. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion); **OR**
  - Second and/or third-degree atrioventricular (AV) block; **OR**
- The device is an **implantable cardioverter-defibrillator (ICD)** and **ALL** of the following[2,3]:
  - **ANY** of the following:
    - Subcutaneous (S-ICD) system; **OR**
    - Traditional (transvenous) ICD; **AND**
  - Transient or reversible causes excluded; **AND**
  - **ANY** of the following:
    - History of **ANY** of the following:
      - An episode of sustained ventricular tachycardia (VT), either spontaneous or induced by an electrophysiology (EP) study, that is not associated with an acute myocardial infarction (MI); **OR**
      - An episode of cardiac arrest due to ventricular fibrillation (VF); **OR**
    - Prior MI with **ALL** of the following:

- Measured left ventricular ejection fraction (LVEF) of less than or equal to 30%; **AND**
- Formal shared decision-making encounter between the patient and a physician (or qualified non-physician practitioner such as a physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation; **AND**
- Absence of NYHA class IV heart failure (HF); **AND**
- Absence of clinical symptoms and findings that would make the patient a candidate for coronary revascularization; **AND**
- Within the last 3 months, no history of coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting[B]; **AND**
- Within the last 40 days, no history of MI[B]; **OR**

■ Severe, ischemic, dilated cardiomyopathy with **ALL** of the following:
- Absence of personal history of sustained VT or cardiac arrest due to VF; **AND**
- NYHA Class II or III heart failure; **AND**
- LVEF less than or equal to 35%; **AND**
- Absence of clinical symptoms and findings that would make them a candidate for coronary revascularization; **AND**
- Formal shared decision-making encounter between the patient and a physician (or qualified non-physician practitioner such as a physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation; **AND**
- Within the last 3 months, no history of coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting; **AND**
- Within the last 40 days, no history of MI; **OR**

■ Severe, non-ischemic, dilated cardiomyopathy with **ALL** of the following:
- Absence of personal history of sustained VT or cardiac arrest due to VF; **AND**
- NYHA Class II or III heart failure; **AND**
- LVEF less than or equal to 35%; **AND**
- Optimal medical therapy for at least 3 months; **AND**

        - Formal shared decision-making encounter between the patient and a physician (or qualified non-physician practitioner such as a physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation; **AND**
        - Absence of clinical symptoms and findings that would make them a candidate for coronary revascularization; **AND**
        - Within the last 3 months, no history of coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting; **AND**
        - Within the last 40 days, no history of MI; **OR**
    - Documented, familial or genetic disorders that confer a high risk of life-threatening tachyarrhythmias (e.g., sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy and **the following:**
        - Formal shared decision-making encounter between the patient and a physician (or qualified non-physician practitioner such as a physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial ICD implantation; **OR**
    - As an adjunct to bridge-to-transplant/bridge-to-LVAD therapy among patients with symptomatic advanced heart failure[15-19]; **OR**
    - For replacement of an existing ICD when **ANY** of the following is **TRUE:**
        - Required due to end of battery life; **OR**
        - Elective replacement indicator (ERI); **OR**
        - Device malfunction (including leads); **OR**
- The device is for **cardiac resynchronization therapy (CRT)[C] without a defibrillator (CRT-P) or with a defibrillator (CRT-D[D], when cardioverter-defibrillator function is indicated)** when **ANY** of the following is **TRUE**[5]:
    - For initial CRT when **ANY** of the following is **TRUE**:
        - LVEF less than or equal to 35% (with ischemic or non-ischemic cardiomyopathy) and **ALL** of the following:
            - No reversible causes; **AND**
            - QRS greater than or equal to 150 ms; **AND**
            - Any type bundle branch block with evidence of dyssynchrony; **AND**

- NYHA III or ambulatory IV HF on maximally tolerated guideline-directed medical therapy (GDMT) for at least 3 months; **OR**
- LVEF less than or equal to 35% and **ALL** of the following:
  - No reversible causes; **AND**
  - QRS greater than or equal to 150 ms; **AND**
  - Left bundle branch block (LBBB); **AND**
  - NYHA classes II, III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**
- LVEF less than or equal to 35% and **ALL** of the following:
  - No reversible causes; **AND**
  - QRS 130-149 ms; **AND**
  - LBBB; **AND**
  - NYHA class II, III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**
- Atrial fibrillation (AF) **OR** sinus rhythm and **ALL** of the following:
  - **ANY** of the following:
    - An indication for ventricular pacemaker implant for second or third-degree AV block (including those who have or will have AV nodal ablation); **OR**
    - Very prolonged first-degree block (e.g., PR greater than 300 ms); **AND**
  - Anticipated frequent ventricular pacing; **AND**
  - EF less than 50%; **AND**
  - NYHA class I, II, or III; **OR**

- For upgrade to a CRT device when **ALL** of the following are **TRUE**:
  - The patient is being paced from the RV greater than 40% of the time; **AND**
  - LVEF less than or equal to 40%; **AND**
  - Worsening HF symptoms (NYHA class II to IV); **OR**
- For replacement of an existing CRT device when **ANY** of the following is **TRUE**:
  - Required due to end of battery life; **OR**
  - Elective replacement indicator (ERI); **OR**
  - Device malfunction (including leads).

[A]NOTE: Patients who meet criteria for cardiac pacemakers, and who also meet the criteria for ICDs, may receive the combined devices in 1 procedure, at the time the biventricular pacemaker is clinically indicated.[2]

[B]NOTE: For patients who meet all criteria for a cardiac pacemaker and an ICD, there is an exception to waiting periods for patients who have had a CABG (or PCI with angioplasty and/or stenting) within the past 3 months, or who have had an MI within the past 40 days. These patients may receive the combined devices in one procedure at the time the pacemaker is clinically indicated.[2]

[C]NOTE:

- In patients with atrial fibrillation (AF) and heart failure (HF) for whom CRT is planned, narrative in the medical record is expected regarding plans for AF control so that CRT may be most effective. It is understood that the future for such patients cannot be predicted and thus future therapy cannot be defined precisely; however, a reference to the need for focus on AF control is desirable.[5]
- HF with concomitant moderate-severe chronic obstructive pulmonary disease (COPD) should have documentation addressing a reasonable hope for CRT response with a clinically guided rationale that the dyspnea is at least in part significantly related to HF.[5]
- Patients with end-stage/advanced renal disease may benefit less from CRT. Documentation regarding the risk-benefit balance in these patients would also be expected.[5]

[D]NOTE: Patients receiving CRT-D must meet criteria for both CRT and ICD implantation for the defibrillator portion of their therapy.[5]

Non-Indications

A **cardiac implantable device** is not considered appropriate if **ANY** of the following is **TRUE**:

- **Implantable pacemakers** with **ANY** of the following[1]:
  - Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia; **OR**
  - Asymptomatic first-degree atrioventricular block; **OR**
  - Asymptomatic sinus bradycardia; **OR**

- Asymptomatic sino-atrial block or asymptomatic sinus arrest; **OR**
- Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) WITHOUT symptomatic bradycardia; **OR**
- Asymptomatic second-degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart); **OR**
- Syncope of undetermined cause; **OR**
- Bradycardia during sleep; **OR**
- Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block; **OR**
- Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy; **OR**
- Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia; **OR**
- A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged; **OR**

- **Implantable defibrillators** with **ANY** of the following[2,3]:
  - Substernal (extravascular/EV-ICD) defibrillators; **OR**
  - Shock from any etiology; **OR**
  - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate; **OR**
  - Significant, irreversible brain damage; **OR**
  - Noncardiac disease, such as cancer, renal failure, or liver failure, that is associated with the possibility of survival of less than 1 year; **OR**
- **Cardiac resynchronization therapy (CRT)** is **NOT** considered appropriate when **ANY** of the following is **TRUE**[5]:
  - Patients with a QRS less than 130 ms (Exception to this non-coverage criterion would be in the case of patients undergoing AV nodal ablation or in need of RV pacing [due to second- or third-degree block or very long first degree block] that is expected to occur a majority of the time); **OR**
  - EF greater than 50%; **OR**
  - Non-ambulatory NYHA IV HF symptoms; **OR**
  - Chronic inotropic HF therapy; **OR**

- LV assist device (LVAD) in place.

Definitions

- **Left ventricular ejection fraction** (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography.[1]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33206	Insertion of permanent atrial pacemaker with transvenous electrode
33207	Insertion of permanent ventricular pacemaker with transvenous electrode
33208	Insertion of permanent atrial and ventricular pacemaker with transvenous electrode
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 with connection to existing single lead
33213	Insertion of pacemaker pulse generator with connection to existing dual leads
33214	Conversion of single chamber implanted pacemaker system to dual chamber system
33216	Insertion of transvenous electrode of permanent pacemaker
33217	Insertion of 2 transvenous electrodes of permanent cardioverter-defibrillator

33221	Insertion of pacemaker pulse generator with existing multiple leads
33224	Transvenous insertion of pacing electrode for left ventricular pacing, with connection to existing pacemaker
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)
33227	Removal and replacement of permanent pacemaker pulse generator in single lead system
33228	Removal and replacement of permanent pacemaker pulse generator in dual lead system
33229	Removal and replacement of permanent pacemaker pulse generator in multiple lead system
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33233	Removal of permanent pacemaker pulse generator
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular
33235	Removal of transvenous pacemaker electrode(s); dual lead system
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33241	Removal of implantable defibrillator pulse generator

	only
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;

93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)

C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C1900	Lead, left ventricular coronary venous system
C2619	Pacemaker, dual chamber, nonrate-responsive (implantable)
C2620	Pacemaker, single chamber, nonrate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and

	programming or reprogramming of sensing or therapeutic parameters)
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for implantable cardioverter defibrillators (ICDs) may include:

- Patients with NYHA Class IV heart failure that is not responsive to medication and who are not candidates for left ventricular assist device (LVAD) who undergo ICD placement are at risk for cardiac decompensation and pump failure - risks which may outweigh the possible benefit of avoiding sudden cardiac death through ICD placement. Individualized patient selection is important for these critically ill patients in order to ensure the patient's goals of care align with their treatment plan, which may include the use of an ICD.[7,15]

The clinical benefits of using these criteria for implantable cardioverter defibrillators (ICDs) may include:

- Improved patient selection resulting in better long-term outcomes. An ICD may serve as an adjunct to "bridge" to heart transplantation which, if successful, may grant the patient years of hospital-free survival. Donor organs are an extremely limited resource. By "bridging" critically ill heart failure patients to transplantation with an ICD (thereby preventing sudden cardiac death), more patients may be able to access optimal donor organs and therefore live longer despite their disease.[15-19]
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

A 2021 study by Robinson et al. examined the use of implantable cardioverter defibrillators (ICDs) among pediatric patients. In this multicenter retrospective analysis, a total of 106 patients with a median age of 14.7 years were enrolled. The authors evaluated the appropriate deployment of ICD shocks as a proxy for appropriate implantation of the ICD itself toward the prevention of sudden cardiac death (SCD). With a median follow-up period of 3 years, 15% of patients received inappropriate shocks. Younger age and positive exercise stress test were associated with appropriate shocks. The authors emphasized the importance of careful patient selection and individualized risk stratification when ICD therapy is being considered, particularly among pediatric patients.[20]

Al-Khatib et al. (2017) published guidelines on behalf of the American Heart Association (AHA), American College of Cardiology (ACC), and the Heart Rhythm Society (HRS) regarding the management of patients with ventricular arrhythmias (VAs) and the prevention of SCD. Various types of defibrillators were discussed, and their effectiveness in terminating life-threatening VAs. Survivors of cardiac arrest, patients with ventricular tachycardia (VT) and structural heart disease, and those with significant left ventricle (LV) dysfunction may benefit greatly from defibrillator implantation.[11]

Kusumoto et al. (2018) published recommendations for the treatment of bradycardia in a multi-society guideline. They strongly recommended permanent pacing regardless of symptoms in patients with acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular (AV) block not attributable to reversible or physiologic causes. Strong recommendations were made for other patients with AV block, including those with neuromuscular disease and symptomatic bradycardia.[12]

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the AHA, ACC, and HRS on the *Management of Patients with Atrial Fibrillation*. A number of recommendations were made or revised for optimum management of atrial fibrillation (AF). Pacemakers are

recommended in AF patients for the treatment of symptomatic bradycardia, which is often related to sick sinus syndrome. The authors stated that antiarrhythmic therapy may exacerbate sick sinus syndrome, requiring pacemaker implantation. Permanent pacing was not recommended by the group for the prevention of AF in patients without other indications for pacemaker placement. Implanted defibrillators are not recommended for AF rhythm control.[13]

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Clinical Guideline Revision History/Information

Original Date: May 26, 2024		
Review History		
Version 2	6/11/2023	422.101 Disclaimer Added
Version 3	6/26/2025	Annual review. Pacemaker criteria replaced with verbatim NCD language. ICD criteria replaced with verbatim NCD language, including removal of subcutaneous section (CMS decision memo asserts that NCD applies in the same manner to both subcutaneous and transvenous/traditional systems) and removal of distinction between primary and secondary prevention of sudden cardiac death (NCD does not distinguish between these uses). CRT criteria replaced with verbatim LCD language. Four relevant notes added (verbatim) from CMS documents. Literature review - Description, Harms & Benefits, and Medical Evidence sections updated (including references).