



## **Cohere Medicare Advantage Policy – Cardiac Implantable Devices**

*Clinical Guidelines for Medical Necessity Review*

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## Guideline Information:

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# Medical Necessity Criteria

## ***Service: Cardiac Implantable Devices***

### **Benefit Category**

Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.<sup>1</sup>

### **Recommended Clinical Approach**

Pacemaker implantation is often indicated for various symptomatic cardiac conduction system abnormalities such as sinus node dysfunction (SND), atrioventricular (AV) block, and atrial fibrillation (AF) with a slow ventricular heart rate response whether due to intrinsic conduction system disease, secondary to medications, or produced by an AV node ablation<sup>2</sup>. Depending on the clinical status and comorbidities of the patient, the patient may require either single-site or multiple-site pacing, added defibrillator function if there are appropriate indications [e.g., heart failure with reduced ejection fraction (HFrEF)], or cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CDT-D). 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<sup>3</sup>. These advances bring additional questions, including those regarding patient selection, indications, and follow-up for conduction system pacing (CSP) versus CRT via biventricular (BiV) pacing.<sup>4</sup>

There is no indication of a defibrillation function for atrial fibrillation alone. Dual-chamber pacing may assist patients with sick sinus syndrome associated with atrial fibrillation. Adequate atrial pacing may reduce the frequency of atrial fibrillation events; however, pacemaker functions that attempt to treat episodes of atrial fibrillation actively have not shown consistent effectiveness. Therefore, pacing is not recommended as a primary treatment for atrial fibrillation. Many antiarrhythmics used to control atrial

fibrillation can exacerbate sick sinus syndrome, which may merit pacing to prevent symptomatic bradycardia. Pacing is frequently required after a surgical Maze procedure when much of the normal electrical impulses from the atria are disrupted.<sup>2</sup>

Pacing has an extremely limited role in the setting of atrial flutter. Pacing may assist patients with sick sinus syndrome associated with atrial flutter and, often, atrial fibrillation. Adequate atrial pacing may reduce the frequency of atrial tachyarrhythmic events; however, pacemaker functions that attempt to actively treat episodes of atrial flutter have not shown consistent effectiveness. Many antiarrhythmics used to control atrial flutter/fibrillation can exacerbate sick sinus syndrome, which may require pacing to prevent symptomatic bradycardia.<sup>5-6</sup>

Implantable cardioverter-defibrillators (ICDs) may be used for secondary prevention of sudden cardiac death/sudden cardiac arrest (SCD/SCA) (e.g., after an individual has experienced such an episode). Primary prevention involves the implantation of an ICD in an individual at high-risk for SCD.<sup>7</sup>

### **Evaluation of Clinical Benefits and Potential Harms**

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac implantable devices. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in implanting cardiac devices can lead to increased symptoms and complications, especially in patients with severe arrhythmias or heart failure. Heidenreich et al. emphasized the importance of timely and appropriate use of cardiac devices to manage heart failure effectively.<sup>3</sup>
- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to cardiac structures, anesthetic risk, and the need for repeat or additional procedures due to complications. January et al.

outlined the guidelines for the management of atrial fibrillation, emphasizing the role of cardiac devices in appropriate patients.<sup>9</sup>

- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. The ACC/AHA/HRS guidelines for device-based therapy of cardiac rhythm abnormalities highlight the importance of careful patient selection and procedural techniques to minimize complications.<sup>6</sup>

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to cardiac implantable devices for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Proper use of cardiac devices is crucial for reducing the risk of sudden cardiac death and other adverse events in patients with ventricular arrhythmias.<sup>7</sup>
- Enhanced diagnostic accuracy: This is crucial for complex arrhythmias such as atrial fibrillation and ventricular arrhythmias. Accurate diagnostics and treatment planning help to prevent complications and improve patient outcomes. The guidelines by Heidenreich et al. and January et al. highlight the benefits of cardiac devices for managing heart failure and arrhythmias.<sup>3,9</sup>
- Reduction in complications and adverse effects: Proper use of cardiac implantable device criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Shen et al. reported on the management of syncope, highlighting the role of cardiac devices in improving patient outcomes.<sup>10</sup>
- Enhanced overall patient satisfaction: Ensuring that cardiac implantable devices are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. Russo et al. reported on the appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy, emphasizing the importance of appropriate use in improving patient outcomes.<sup>16</sup>

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

## Medical Necessity Criteria

### Indications

→ **Cardiac implantable devices** are considered appropriate if **ANY** of the following is **TRUE**<sup>2,6,8-9</sup>:

- ◆ The device is an **implantable single or dual-chamber pacemaker**, and **ANY** of the following is **TRUE**:
  - The patient has symptomatic persistent or permanent atrial fibrillation and is a candidate for AV node ablation; **OR**
  - The patient has documented non-reversible symptomatic bradycardia due to sinus node dysfunction; **OR**
  - The patient has documented non-reversible symptomatic bradycardia due to second-degree and/or third-degree atrioventricular block; **OR**
  - Asymptomatic second-degree atrioventricular block of Mobitz Type I, and **ANY** of the following:
    - QRS complexes are prolonged; **OR**
    - Electrophysiological studies have demonstrated block is at or beyond the level of HIS Bundle (a component of the electrical conduction system of the heart); **OR**
  - Frequent or persistent supraventricular tachycardias (e.g., AV nodal reentrant tachycardia, atrial flutter, atrial fibrillation), and pacemaker is specifically for control of tachycardia<sup>1</sup>; **OR**
  - For patients with tachy-brady syndrome and symptoms attributable to bradycardia, permanent pacing is

reasonable to increase heart rate and reduce symptoms attributable to hypoperfusion<sup>8</sup>; **OR**

- In patients with acquired second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block not attributable to reversible or physiologic causes, permanent pacing is recommended regardless of symptoms<sup>8</sup>; **OR**
- In patients with neuromuscular diseases associated with conduction disorders, including muscular dystrophy (e.g., myotonic dystrophy type 1) or Kearns-Sayre syndrome, who have evidence of second-degree atrioventricular block, third-degree atrioventricular block, or an HV interval of 70 ms or greater, regardless of symptoms, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is recommended; **OR**
- In patients with infiltrative cardiomyopathy, such as cardiac sarcoidosis or amyloidosis, and second-degree Mobitz type II atrioventricular block, high-grade atrioventricular block, or third-degree atrioventricular block, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is reasonable; **OR**
- In patients with lamin A/C gene mutations, including limb-girdle and Emery-Dreifuss muscular dystrophies, with a PR interval greater than 240 ms and LBBB, permanent pacing, with additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, is reasonable; **OR**
- In patients with marked first-degree or second-degree Mobitz type I (Wenckebach) atrioventricular block with symptoms that are clearly attributable to the atrioventricular block, permanent pacing is reasonable; **OR**
- For patients in sinus rhythm with a single chamber ventricular pacemaker who develop pacemaker syndrome, revising to a dual chamber pacemaker is recommended; **OR**
- Alternating bundle branch block; **OR**
- In patients with Anderson-Fabry disease and QRS prolongation greater than 110 ms, permanent pacing, with

additional defibrillator capability if needed and meaningful survival of greater than 1 year is expected, may be considered; **OR**

- Syncope and bundle branch block who are found to have an HV interval 70 ms or greater or evidence of infranodal block at EPS; **OR**
- Vasovagal syncope with **ALL** of the following<sup>10</sup>:
  - The patient is 40 years of age or older; **AND**
  - Recurrent vasovagal syncope; **AND**
  - Prolonged spontaneous pauses (documented spontaneous pauses greater than or equal to 3 seconds correlated with syncope or an asymptomatic pause greater than or equal to 6 seconds); **OR**
- Permanent cardiac pacing is reasonable in patients with carotid sinus syndrome that is cardioinhibitory (asystole is greater than 3 seconds or if there is AV block) or mixed with a significant vasodepressor response (greater than or equal to 50 mmHg drop in systolic blood pressure); **OR**
- Previously implanted pacemaker replacement for **ANY** of the following:
  - Infection-related to leads or device; **OR**
  - Battery life ended; **OR**
  - Malfunction of lead or device; **OR**
  - Manufacturer recall of device; **OR**
- ◆ The device is an **implantable cardioverter-defibrillator (ICD)** and **ALL** of the following<sup>5,7,10-11</sup>:
  - Transient or reversible causes excluded; **AND**
  - **ANY** of the following:
    - **Primary prevention of sudden cardiac death (SCD)** with **ALL** of the following:
      - ◆ The patient is expected to have meaningful survival of greater than one year; **AND**
      - ◆ **ANY** of the following<sup>5,7,10-11</sup>:
        - In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days post MI and at least 90 days post revascularization, and with New York Heart Association (NYHA) class I heart

failure (HF) despite guideline-directed medical therapy (GDMT)<sup>1</sup>; **OR**

- In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days post-MI and at least 90 days post revascularization, and with NYHA class II or III HF despite GDMT; **OR**
- Patients with documented prior MI with nonsustained ventricular tachycardia (NSVT), LVEF less than or equal to 40%, and ventricular fibrillation (VF) or ventricular tachycardia (VT) was induced during an electrophysiology (EP) study; **OR**
- In nonhospitalized patients with heart failure with reduced ejection fraction (HFrEF) and NYHA class IV symptoms and/or use of inotropes, and who are candidates for cardiac transplantation or an LVAD; **OR**
- In patients with nonischemic cardiomyopathy (NICM) or neuromuscular disorders (Duchenne, Becker, Emery-Dreifuss, Myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I) and formal shared decision-making encounter between patient and physician or qualified non-physician practitioner or neuromuscular disorders (Duchenne, Becker, Emery-Dreifuss, Myotonic type 1, and limb-girdle types 1B, 2C, 2F, and 2I), HF with NYHA class II-III symptoms and an LVEF of 35% or less, despite GDMT; **OR**
- In patients with NICM due to a Lamin A/C mutation who have 2 or more risk factors (NSVT, LVEF less than 45%, non-missense mutation, and male sex); **OR**
- In patients with NICM or Neuromuscular disorders (Duchenne, Becker,

- Emery–Dreifuss, Myotonic type 1, and limb–girdle types 1B, 2C, 2F, and 2I), HF with NYHA class I symptoms and an LVEF of 35% or less despite GDMT, an ICD may be considered; **OR**
- In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%), an ICD is recommended; **OR**
- In patients with hypertrophic cardiomyopathy (HCM) or long QT syndrome, an ICD is reasonable after a formal shared decision-making encounter between patient and physician or a qualified non-physician practitioner; **OR**
- **Secondary prevention of SCD** with **ALL** of the following [5.8.10-11](#):
  - ◆ The patient is expected to have meaningful survival of greater than one year; **AND**
  - ◆ **ANY** of the following:
    - In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes, an ICD is recommended; **OR**
    - In patients with ischemic heart disease and unexplained syncope who have an LVEF less than or equal to 35%, an ICD is recommended; **OR**
    - In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT; **OR**

- In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%), an ICD is recommended; **OR**
- In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended; **OR**
- In patients with a cardiac channelopathy (e.g., long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, Brugada syndrome, early repolarization syndrome, and short QT syndrome) and SCA, an ICD is recommended; **OR**
- Hemodynamically unstable VT; **OR**
- Stable sustained VT not associated with myocardial infarction (MI); **OR**
- In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker, treatment intensification with either combination medication therapy (e.g., beta blocker, flecainide), left cardiac sympathetic denervation, and/or an ICD is recommended; **OR**
- In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA, or a recent history of syncope presumed due to VA, an ICD is recommended; **OR**
- In patients with early repolarization pattern on ECG and cardiac arrest or

sustained VA, an ICD is recommended;

**OR**

- In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended; **OR**
- In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended; **OR**
- In patients with adult congenital heart disease and hemodynamically unstable VT, an ICD is recommended after evaluation and appropriate treatment for residual lesions/ventricular dysfunction; **OR**
- In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended; **OR**
- In adults with repaired tetralogy of Fallot physiology and inducible VT/VF or spontaneous sustained VT, implantation of an ICD is reasonable; **OR**

◆ The device is a **subcutaneous implantable cardioverter-defibrillator system** and the following<sup>7</sup>:

- Indication for ICD as listed above **AND ANY** of the following:
  - Recommended (Class I indication): If pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated and **ANY** of the following:
    - ◆ Vascular access is limited; **OR**
    - ◆ The patient is immunocompromised; **OR**
    - ◆ The patient is at high-risk for bacteremia (e.g., hemodialysis, chronic indwelling endovascular catheters); **OR**
    - ◆ The patient has endocarditis; **OR**
  - Reasonable (Class IIa indication): If pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated; **OR**

- ◆ The device is for **cardiac resynchronization therapy (CRT) without a defibrillator (CRT-P) or with a defibrillator (CDT-D, when cardioverter-defibrillator function is indicated)** when **ANY** of the following is **TRUE**<sup>3,12-16</sup>:
  - 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<sup>3,12</sup>:
      - ◆ Sinus rhythm; **AND**
      - ◆ QRS greater than or equal to 150 ms; **AND**
      - ◆ LBBB; **AND**
      - ◆ NYHA class II, 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:
      - ◆ Sinus rhythm; **AND**
      - ◆ QRS greater than or equal to 150 ms; **AND**
      - ◆ Non-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:
      - ◆ Sinus rhythm; **AND**
      - ◆ QRS 120–149 ms; **AND**
      - ◆ LBBB; **AND**
      - ◆ NYHA class 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:
      - ◆ Sinus rhythm **AND**
      - ◆ QRS 120–149 ms; **AND**
      - ◆ Non-LBBB; **AND**
      - ◆ NYHA class III, or ambulatory IV HF on maximally tolerated GDMT for at least 3 months; **OR**
    - LVEF less than or equal to 30% and **ALL** of the following:
      - ◆ Ischemic cause of HF; **AND**
      - ◆ Sinus rhythm **AND**
      - ◆ QRS greater than or equal to 150 ms; **AND**

- ◆ LBBB; **AND**
- ◆ NYHA class I 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, including those who have or will have AV nodal ablation); **OR**
    - Very prolonged first-degree block (e.g., PR greater than 300 ms); **OR**
  - ◆ **ANY** of the following:
    - Pharmacological rate control will allow near 100% ventricular pacing with CRT; **OR**
    - Anticipated frequent ventricular pacing;
- AND**
- ◆ EF less than 50%; **AND**
- ◆ NYHA class I, II, or III; **OR**
- The patient has a QRS less than 130 ms, and **ANY** of the following:
  - ◆ Undergoing AV nodal ablation; **OR**
  - ◆ In need of right ventricle pacing (due to second-degree or third-degree block or very long first-degree block); **OR**
- High degree or complete heart block and EF 36% to 50% (**applies to CRT-P only**); **OR**
- New pacemaker implantation with **ALL** of the following:
  - ◆ LVEF less than or equal to 35% on GDMT; **AND**
  - ◆ Anticipated requirement for significant (greater than 40%) ventricular pacing; **OR**
- For upgrade to a CRT device when **ALL** of the following are **TRUE**<sup>12</sup>:
  - 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**<sup>12</sup>:
  - Required due to end of battery life; **OR**
  - Elective replacement indicator (ERI); **OR**
  - Device malfunction (including leads).

## Non-Indications

→ **Cardiac implantable devices** are not considered appropriate if **ANY** of the following is **TRUE**:

◆ **Implantable pacemakers** are **NOT** considered appropriate for **ANY** of the following<sup>1</sup>:

- 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.

◆ **Implantable defibrillators** are **NOT** considered appropriate for **ANY** of the following:

- VT due to a completely reversible disorder (electrolyte imbalance, drug use); **OR**
  - Active systemic or local infection; **OR**
  - NYHA class IV patients with heart failure not responsive to medication and are not candidates for heart transplantation or LVAD<sup>7,10</sup>; **OR**
  - Noncardiac disease, such as cancer or liver failure, is associated with the possibility of survival of less than 1 year.
- ◆ **Subcutaneous implantable defibrillator systems** are **NOT** considered appropriate for **ANY** of the following:
- In patients with an indication for bradycardia pacing or CRT; **OR**
  - Anti-tachycardia pacing for VT termination is required; **OR**
- ◆ **Cardiac resynchronization therapy (CRT)** is **NOT** considered appropriate when **ANY** of the following is **TRUE**<sup>3,12</sup>:
- EF greater than 50%; **OR**
  - Non-ambulatory NYHA IV HF symptoms; **OR**
  - Chronic inotropic HF therapy; **OR**
  - With an LV assist device already in place.

### 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

## Medical Evidence

January et al. (2014) published an evidence-based, systematic review and subsequent guidelines for the American Heart Association, American College of Cardiology, and the Heart Rhythm Society, titled *Management of Patients with Atrial Fibrillation*. A number of recommendations were made or revised for optimum management of atrial fibrillation. Pacemakers are recommended in AF patients for the treatment of symptomatic bradycardia, which is often related to sick sinus syndrome. They state 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 atrial fibrillation rhythm control.<sup>9</sup>

Calkins et al. (2017) published an expert consensus statement with the Heart Rhythm Society, the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society to update guidelines based on advances in atrial fibrillation ablation since their previous publication. It was recommended that the amount of time an individual spends in AF (24-hour AF burden) is essential to address when ablation is being considered. This is due largely to the increase in implantable loop recorders, pacemakers, and ICDs.<sup>2</sup>

Al-Khatib et al. (2017) performed a systematic review on behalf of the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society regarding the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Various types of defibrillators were discussed and their effectiveness in terminating life-threatening ventricular arrhythmias. Survivors of cardiac arrest, patients with VT and structural heart disease, and those with significant LV dysfunction may benefit greatly from defibrillator implantation.<sup>7</sup>

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 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.<sup>8</sup>

There are two related National Coverage Determinations (NCDs) from the Centers for Medicare and Medicaid Services (CMS):

- *Implantable Automatic Defibrillators (2023)*: Recommendations made for those with a history of SCD, prior MI, and EF measured at less than or equal to 30%, or heart failure without a history of arrest.<sup>11</sup>
- *Cardiac Pacemakers (2004)*: Contains recommendations for pacemaker implantation, both single and dual-chamber, in various chronic, recurrent arrhythmic scenarios.<sup>17</sup>

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# Clinical Guideline Revision History/Information

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