



Cardiac Implantable Devices – Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Cardiac Implantable Devices

General Guidelines

- **Units, Frequency, & Duration:** Once
- **Criteria for Subsequent Requests:** Subsequent requests may be considered for device replacement due to battery end-of-life (EOL) or elective replacement interval (ERI), replacement after infection, the clinical need for different pacing modes, or replacement after manufacturer recall.
- **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 ablation¹. 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 (CRT-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 sequence¹⁰. 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.¹⁷

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.¹

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.²⁻³

Implantable cardioverter-defibrillators (ICDs) may be used for secondary prevention of sudden cardiac death/sudden cardiac arrest (SCD/SCA), i.e., after an individual has experienced such an episode. Primary prevention involves the implantation of an ICD in an individual at high-risk for SCD.⁴

- **Exclusions:** Permanent pacing is typically performed for symptomatic bradyarrhythmias, although 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 symptoms⁶. Both sleep disorders of breathing and nocturnal bradycardias are relatively common, and treatment of sleep apnea not only reduces the frequency of these arrhythmias but also may offer cardiovascular benefits. The presence of nocturnal bradycardias should prompt consideration for screening for sleep apnea, beginning with solicitation of suspicious symptoms. However, nocturnal bradycardia is not in itself an indication for permanent pacing.⁵ Atrial fibrillation should only be the primary indication for pacemaker implantation when performed in concert with AV node ablation. Isolated pacemaker

insertion should not be requested with atrial fibrillation or atrial flutter as the only associated diagnosis. Pacing is a treatment for symptomatic bradycardic rhythms. Leadless pacemakers are beyond the scope of this policy.

Medical Necessity Criteria

Indications

→ **Cardiac implantable devices** are considered appropriate if **ANY** of the following is **TRUE**^{1,3,5-6}:

- ◆ 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**
 - In patients with permanent AF and symptomatic bradycardia, permanent pacing is recommended; **OR**
 - The patient has atrial flutter with documented and serious associated sinus node dysfunction, AV node dysfunction, or symptomatic bradycardia, with or without antiarrhythmic treatment²⁻³; **OR**
 - The patient has symptomatic bradycardia, sinus node dysfunction, or AV node dysfunction with or without antiarrhythmic treatment or guideline-directed management and therapy for which there is no alternative treatment and continued treatment is clinically necessary⁵; **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 hypoperfusion⁵; **OR**
 - In patients with symptomatic chronotropic incompetence, permanent pacing with rate-responsive programming is reasonable to increase exertional heart rates and improve symptoms⁵; **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 symptoms⁵; **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 an 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**
- In patients with atrioventricular block who have an indication for permanent pacing with a left ventricular ejection fraction (LVEF) between 36% and 50% and are expected to require ventricular pacing less than 40% of the time, it is reasonable to choose right ventricular pacing over pacing methods that maintain physiologic ventricular activation (e.g., CRT or His bundle pacing); **OR**

- Alternating bundle branch block; **OR**
- In patients with Kearns–Sayre syndrome and conduction disorders, permanent pacing is reasonable, with additional defibrillator capability if appropriate and meaningful survival of greater than 1 year is expected; **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 following²:
 - 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^{2,4,7–8}:
 - 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^{2,4,7-8}:
 - 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)⁸; **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 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**
 - 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), 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 <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) and **ANY** of the following risk factors, an ICD is reasonable:
 - Maximum LV wall thickness greater than or equal to 30 mm; **OR**
 - SCD in 1 or more first-degree relatives presumably caused by HCM; **OR**
 - One or more episodes of unexplained syncope within the preceding 6 months; **OR**
- In patients with HCM who have spontaneous NSVT or an abnormal blood pressure response with exercise, who also have additional SCD risk modifiers or high risk features, an ICD is reasonable; **OR**
- In patients with HCM who have NSVT or an abnormal blood pressure response with exercise but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain; **OR**
- In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study

and to implant an ICD, if a sustained ventricular arrhythmia (VA) is inducible;

OR

- In patients with cardiac sarcoidosis who have an indication for permanent pacing, implantation of an ICD can be beneficial;

OR

- In patients with a heart transplant and severe allograft vasculopathy with LV dysfunction, an ICD may be reasonable;

OR

- In patients with Emery-Dreifuss and limb-girdle type IB muscular dystrophies with progressive cardiac involvement, an ICD is reasonable; **OR**
- In patients with myotonic dystrophy type 1 with an indication for a permanent pacemaker, an ICD may be considered to minimize the risk of SCA from VT; **OR**
- In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated, intensification of therapy with additional medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation, and/or an ICD is recommended; **OR**
- In asymptomatic patients with long QT syndrome and a resting QTc greater than 500 ms while receiving a beta blocker, intensification of therapy with medications (guided by consideration of the particular long QT syndrome type), left cardiac sympathetic denervation or an ICD may be considered; **OR**
- In patients with adult congenital heart disease and severe ventricular dysfunction (LVEF less than 35%) and symptoms of heart failure despite GDMT

or additional risk factors, ICD implantation may be considered; **OR**

- **Secondary prevention of SCD** with **ALL** of the following^{2-5,7-8}:
 - ◆ 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 inducible sustained monomorphic VT on electrophysiological study, 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 NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD; **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 arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to ventricular arrhythmia (VA), an ICD can be useful; **OR**
- In patients with hypertrophic cardiomyopathy (HCM) who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise, an ICD is recommended; **OR**
- In patients with giant cell myocarditis with VF or hemodynamically unstable VT treated according to GDMT, an ICD and/or an antiarrhythmic medication may be considered; **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 cardiac sarcoidosis and LVEF greater than 35% who have syncope and/or evidence of myocardial scar by cardiac MRI or positron emission tomographic (PET) scan, and/or have an indication for permanent pacing, implantation of an ICD is reasonable; **OR**
- In patients with an LVAD and sustained VA, an ICD can be beneficial; **OR**
- In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated, an ICD is reasonable; **OR**
- In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable; **OR**
- In patients with a cardiac channelopathy (i.e., 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**
- The patient's risk of death from a ventricular arrhythmia (VA) is deemed high and risk of non-arrhythmic death is deemed low based on comorbidities; **OR**
- Unexplained syncope and ischemic heart disease with inducible sustained monomorphic VT on EP study; **OR**
- Diagnosed condition with high-risk of life-threatening VT (familial or inherited); **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**
 - In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA; **OR**
- ◆ The device is a **subcutaneous implantable cardioverter-defibrillator system** and **ANY** of the following⁴:
- 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**^{5.9-14}:
 - 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^{9.10}:
 - ◆ 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) 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**
 - Pharmacological rate control will allow near 100% ventricular pacing with CRT; **AND**
 - ◆ With an EF less than or equal to 35% on maximally tolerated GDMT for at least 3 months; **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 **TRUE⁹**:
 - The patient is being paced from the RV greater than 40% of the time; **AND**
 - LVEF less than or equal to 35% on GDMT; **OR**
- For replacement of an existing CRT device when **ANY** of the following is **TRUE⁹**:
 - 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:

- The patient has any form of atrial fibrillation and does not meet the criteria for an AV node ablation; **OR**

- The patient has atrial fibrillation or atrial flutter without other conduction abnormalities, which would merit permanent pacing; **OR**
 - In patients with permanent or persistent AF in whom a rhythm control strategy is not planned, implantation of an atrial lead should not be performed
 - Asymptomatic bradyarrhythmias unless associated 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; **OR**
 - In patients with first-degree atrioventricular block or second-degree Mobitz type I (Wenckebach) or 2:1 atrioventricular block which is believed to be at the level of the atrioventricular node, without symptoms or symptoms that do not temporally correspond to the atrioventricular block, permanent pacing should not be performed
 - Prevention of atrial fibrillation⁶; **OR**
 - Treatment of sleep apnea¹⁵; **OR**
 - Bradycardia during sleep⁸; **OR**
 - Syncope of undetermined cause¹⁶; **OR**
 - Reversible or transient causes of bradycardia (acute myocardial infarction, drug toxicity, electrolyte abnormalities)¹⁶; **OR**
- ◆ **Implantable defibrillators** are **NOT** considered appropriate for **ANY** of the following:
- VT due to 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^{4,8}; **OR**
 - Noncardiac disease such as cancer or liver failure, associated with possibility of survival less than one (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**
 - Antitachycardia pacing for VT termination is required; **OR**

- ◆ **Cardiac Resynchronization Therapy (CRT)** is **NOT** considered appropriate when **ANY** of the following is **TRUE**^{9,10}:
- QRS less than 120 ms; **OR**
 - EF greater than 50%; **OR**
 - Non-ambulatory NYHA IV HF symptoms; **OR**
 - Chronic inotropic HF therapy; **OR**
 - With LV assist device already in place; **OR**
 - Active systemic or local infection.

Site of Service Criteria

Outpatient or Inpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
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
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging

	guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
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
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, for 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.⁶

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 the use of implantable loop recorders, pacemakers, and ICDs.¹

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.⁴

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.⁵

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.⁸
- *Cardiac Pacemakers* (2004): Contains recommendations for pacemaker implantation, both single and dual-chamber, in various chronic, recurrent arrhythmic scenarios.¹⁶

References

1. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary. *J Arrhythm*. 2017 Oct;33 (5): 369–409. doi: 10.1016/j.joa.2017.08.001. PMID: 29021841; PMCID: PMC5634725.
2. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the management of adult patients with supraventricular tachycardia: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [published correction appears in *Circulation*. 2016 Sep 13;134(11):e234–5]. *Circulation*. 2016;133(14):e506–e574. doi: 10.1161/CIR.0000000000000311. PMID: 26399663.
3. Epstein AE, Dimarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities [published correction appears in *Heart Rhythm*. 2009 Jan;6(1):e2]. *Heart Rhythm*. 2008;5(6):e1–e62. doi: 10.1016/j.hrthm.2008.04.014. PMID: 18534360.
4. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *J Am Coll Cardiol*. 2018 Oct 2;72(14):e91–e220. doi: 10.1016/j.jacc.2017.10.054. PMID: 29097296.
5. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2019;140(8) doi: <https://doi.org/10.1161/cir.0000000000000628>.
6. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. *Circulation*. 2014 Dec 2;130(23):e199–267. doi: 10.1161/CIR.0000000000000041. PMID: 24682347; PMCID: PMC4676081.
7. Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope. *J Am Coll*

Cardiol. 2017 Aug 1;70(5):e39–e110. doi: 10.1016/j.jacc.2017.03.003. PMID: 28286221.

8. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD): Implantable automatic defibrillators (20.4). Published February 15, 2018. Accessed November 10, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
9. Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD): Cardiac resynchronization therapy (L39080). Effective Date December 21, 2021. Accessed December 28, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation* 2022;145(18):e895–e1032. doi: 10.1161/CIR.0000000000001063. PMID: 35363499.
11. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J.* 2021 Sep 21;42(36):3599–3726. doi: 10.1093/eurheartj/ehab368. PMID: 34447992.
12. Glikson M, Nielsen JC, Kronborg MB, et al. 2021 ESC guidelines on cardiac pacing and cardiac resynchronization therapy. *Eur Heart J.* 2021 Sep 14;42(35):3427–3520. doi: 10.1093/eurheartj/ehab364. PMID: 34455430.
13. Madhavan M, Mulpuru SK, McLeod CJ, et al. Advances and future directions in cardiac pacemakers: Part 2 of a 2-part series. *J Am Coll Cardiol.* 2017 Jan 17;69(2):211–235. doi: 10.1016/j.jacc.2016.10.064. PMID: 28081830.
14. Russo AM, Stainback RF, Bailey SR, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: A report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society for Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. *J Am Coll Cardiol.* 2013 Mar 26;61(12):1318–68. doi: 10.1016/j.jacc.2012.12.017. PMID: 23453819.
15. Krahn AD, et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. *Journal of the*

American College of Cardiology 2006;47(2):379–383. DOI:
10.1016/j.jacc.2005.09.026.

16. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD): Cardiac pacemakers (20.8). Published April 30, 2004. Accessed November 10, 2023.
<https://www.cms.gov/medicare-coverage-database/search.aspx>.
17. Chung et al. 2023 HRS/APHRS/LAHRs Guideline on Cardiac Physiologic Pacing for the Avoidance and Mitigation of Heart Failure. *Heart Rhythm*, Vol 20, No 9, September 2023.

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