**Coverage Summary**

**Cardiac Pacemakers and Defibrillators**

<table>
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<tr>
<th>Policy Number: C-001</th>
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**Related Medicare Advantage Policy Guidelines:**

- Anesthesia in Cardiac Pacemaker Surgery (NCD 10.6)
- Cardiac Pacemaker Evaluation Services (NCD 20.8.1)
- Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (NCD 20.8.3)
- External Counterpulsation (ECP) Therapy for Severe Angina (NCD 20.20)
- Implantable Automatic Defibrillators (NCD 20.4)
- Intraoperative Ventricular Mapping (NCD 20.11)
- Leadless Pacemakers (NCD 20.8.4)
- Self-Contained Pacemaker Monitors (NCD 20.8.2)
- Transtelephonic Monitoring of Cardiac Pacemakers (NCD 20.8.1.1)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

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### I. COVERAGE

**Coverage Statement:** Cardiac pacemakers, internal and external pacemakers are covered when Medicare coverage criteria are met.

**DME Face to Face Requirement:** Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including
automatic external defibrillator garment with electronic analysis). For DME Face to Face Requirement information, refer to the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotic (Non-Foot Orthotics) and Medical Supplies Grid.

Guidelines/Notes:

1. **Cardiac Pacemakers (single-chamber or dual chamber)**
   Cardiac pacemakers (single-chamber or dual chamber) are covered when criteria are met.
   - For dates of service March 16, 1983 - August 12, 2013, see the [NCD for Cardiac Pacemaker (20.8)](Accessed April 26, 2018).
   - For dates of services on or after August 13, 2013, see the [NCD for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (20.8.3)](Accessed April 26, 2018).
   - For services for post-implant follow-up and evaluation of implanted cardiac pacemakers; see the [NCD for Cardiac Pacemaker Evaluation Services (20.8.1)](Accessed April 26, 2018).

2. **Leadless Pacemakers (CPT Codes 0387T, 0388T, 0389T, 0390T and 0391T)**
   On January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo stating it will finalize its proposal to cover leadless pacemakers through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when procedures are performed in FDA approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:
   - An associated ongoing FDA approved post-approval study; or
   - Completed an FDA post-approval study.

   Refer to the [NCD for Leadless Pacemakers (NCD 20.8.4)](Accessed April 26, 2018).


   Also see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).


3. **Cardiac Pacemaker Monitoring**
   a. Self-contained pacemaker monitors may be covered when prescribed by the treating physician with a cardiac pacemaker.
      1) Digital electronic pacemaker monitor provides the patient with an instantaneous digital readout of his pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.
      2) Audible/Visible signal pacemaker monitor produces an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services.
until a change occurs in these signals; at such time, the patient contacts his physician.

**Note:** The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

See the [NCD for Self-Contained Pacemaker Monitors (20.8.2)](accessed April 26, 2018)

b. Trans-telephonic cardiac pacemaker monitoring
   1) Limited to lithium battery powered pacemakers
   2) Transtelephonic cardiac monitoring may be done by:
      a) Member’s physician
      b) Outside entity – requires an annually renewed physician’s prescription and may include:
         • Commercial monitoring service
         • Hospital outpatient department
         • Pacemaker clinic
   3) Frequency of monitoring
      a) Responsibility of member’s physician to determine frequency:
      b) Frequency may vary over time and require modifications
   4) In order for trans-telephonic cardiac monitoring services to be covered, the services must consist of the following:
      a) Minimum 30 second readable strip of the pacemaker in the free running mode
      b) Unless contraindicated, a minimum 30 second readable strip of the pacemaker in the magnetic mode
      c) Minimum 30 seconds of readable ECG/EKG strip

See the [NCD for Transtelephonic Monitoring of Cardiac Pacemakers (20.8.1.1)](accessed April 26, 2018).

4. **Implantable Automatic Defibrillators**
   a. An implantable cardioverter defibrillator is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. This therapy has been shown in trials to improve survival and reduce sudden cardiac death in patients with certain clinical characteristics.
   b. **Nationally Covered Indications**
      1. Effective for services performed on or after February 15, 2018 CMS has determined that the evidence is sufficient to conclude that the use of implantable cardioverter defibrillators (ICDs, also referred to as defibrillators) is reasonable and necessary:
         a. **Covered Indications**
            1. Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation. Patients must have demonstrated:
               o An episode of sustained ventricular tachyarrhythmia, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction and not due to a transient or reversible cause; or
2. Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure;
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B2, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B3, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

4. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained ventricular tachyarrhythmia, New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or
qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

For these patients identified in B5, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For each of these groups listed above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);

2. Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;

3. Patients must not have:
   - Significant, irreversible brain damage; or
   - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or
   - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

**Cardiac Pacemakers:** Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in this national coverage determination for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;

**Replacement of ICDs:** Patients with an existing ICD may receive a ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

c. **Other Indications**

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge to transplant to prolong survival until a donor becomes
available is determined by the local Medicare Administrative Contractors (MACs).

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B IDE trials (42 CFR 405.201).

See the CMS Decision Memo dated February 28, 2018 for Implantable Cardioverter Defibrillators (CAG-00157R4). CMS is finalizing changes to the NCD for Implantable Automatic Defibrillators (20.4). (Accessed April 26, 2018)

For claims processing instructions, refer to the Medicare Claims Processing Manual, Chapter 32, §270.1 - Coding Requirements for Implantable Automatic Defibrillators. (Accessed April 26, 2018)

5. Subcutaneous Implantable Automatic Defibrillators (CPT codes 33270, 33271, 33273, 93260, 93261 and 93644)
Subcutaneous implantable automatic defibrillators are covered when criteria in the NCD for Implantable Automatic Defibrillators (20.4) are met. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time. (Accessed April 26, 2018)

6. Automatic External Defibrillators
- Medicare does not have a National Coverage Determination (NCD) for automatic external defibrillators.
- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) for automatic external defibrillators for all 50 states exist and compliance with these policies is required where applicable. All 4 DME MACs have the same coverage criteria for automatic external defibrillators.
- Automatic external defibrillators are covered when criteria are met. For coverage criteria, refer to the DME MAC LCDs for Automatic External Defibrillators (L33690).
- Committee approval date: May 16, 2017
- Accessed November 14, 2018

7. Anesthesia for Cardiac Pacemaker Surgery
Anesthesia for cardiac pacemaker surgery is covered when reasonable and necessary. See the NCD for Anesthesia in Cardiac Pacemaker Surgery (10.6). (Accessed April 26, 2018)

8. Intraoperative Ventricular Mapping
Intraoperative ventricular mapping is covered only for the uses and medical conditions:
- Localize accessory pathways associated with the Wolff-Parkinson-White (WPW) and other preexcitation syndromes;
- Map the sequence of atrial and ventricular activation for drug-resistant supraventricular tachycardias;
- Delineate the anatomical course of His bundle and/or bundle branches during corrective cardiac surgery for congenital heart diseases; and
- Direct the surgical treatment of patients with refractory ventricular tachyarrhythmias.
See the NCD for Intraoperative Ventricular Mapping (20.11). (Accessed April 26, 2018)

9. External Counterpulsation (ECP) Therapy
External counterpulsation (ECP) therapy for severe angina is covered when criteria are met.
See the NCD for External Counterpulsation Therapy for Severe Angina (20.20). (Accessed April
II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

11/20/2018 Re-review with the following update:
Guideline 5 [Subcutaneous Implantable Automatic Defibrillators (CPT codes 33270, 33271, 33273, 93260, 93261 and 93644)] – Removed the following “Note” from guideline (as link to CGS is no longer available):

“Note: In November 2014, CGS published the article, S-ICD Category III CPT Codes: Change in Coverage which states the removal of the ICD category III CPT codes (0319T to 0328T) from LCD L31832, as these codes are included in the NCD and CMS Medicare Claims Processing Manual.”

05/11/2018 Annual review; deleted the following definitions as these definitions are also in the respective reference NCDs:
- External Counterpulsation (ECP)
- Implantable Automatic Defibrillator
- Intraoperative Ventricular Mapping

03/20/2018 Re-review with the following updates:

10/17/2017 Re-review with the following update:
Guideline 2 (Leadless Pacemakers) - removed the reference link to the CMS Decision Memo for Leadless Pacemakers (CAG-00448N); replaced with the reference link to the NCD for Leadless Pacemakers (NCD 20.8.4).

05/16/2017 Annual review with the following update:
Guideline 2 [Leadless Pacemakers (CPT Codes 0387T, 0388T, 0389T, 0390T and 0391T)] – added guideline based on the CMS Decision Memo for Leadless Pacemakers (CAG-00448N) dated January 18, 2017. (new to the policy)

05/17/2016 Annual review with the following updates:
- Guideline 1 (Cardiac Pacemakers) – separated guideline by dates of services
- Guideline 4 (Subcutaneous Implantable Automatic Defibrillators):
  - replaced CPT codes 0319T-0325T with CPT codes 33270, 33271, 33273 93260, 93261 and 93644
  - Added reference link to the CGS Article titled S-ICD Category III CPT Codes: Change in Coverage which states that CGS has removed the 0319T-0328T codes as they are included in the NCD and CMS Medicare Claims Processing Manual.
05/19/2015  Annual review with the following update:
Guideline #3 (Implantable Automatic Defibrillators) – Deleted reference statement to LCDs for *Automatic Implantable Cardiac Defibrillators (AICD)*, LCDs have been retired.

10/21/2014  Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

05/20/2014  Annual review with the following update:
Guideline #4 (Subcutaneous Implantable Automatic Defibrillators) - Replaced guideline with the following: *Subcutaneous implantable automatic defibrillators are covered when criteria in the NCD for Implantable Automatic Defibrillators (20.4) are met. Local Coverage Determinations (LCDs)/Local Articles do not exist at this time.*

10/24/2013  Added language based on the CMS *Decision Memo for Cardiac Pacemakers: Single-Chamber and Dual-Chamber Permanent Cardiac Pacemakers (CAG-00063R3)* to indicate:

On August 13, 2013, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to conclude that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. 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).

Therefore, the following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:
1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction.
2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.

08/20/2013  Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).

06/24/2013  Guidelines 4 (Subcutaneous Implantable Automatic Defibrillators) - Added applicable coverage guidelines (new to policy) with the National Government Services Article for Category III CPT Coverage – Related to LCD L25275 (A46075) as default guidelines for states with no LCDs/Articles

06/18/2012  Annual review; no updates.

06/30/2011  Annual review. Updated Guidelines 3 (Implantable Automatic Defibrillators) to include additional note pertaining to CMS data collection mechanism. Deleted Guidelines #5 Cardiac Resynchronization Therapy for CHF as the only available LCD was retired. CS title was changed to Cardiac Pacemakers and Defibrillators.

02/15/2011  Updated Guidelines 3 (Implantable Automatic Defibrillators) to include the link to the Medicare Claims Processing Manual, Chapter 32, Section and the link to the Medicare
Updated the link of the L12193, LCD for Resynchronization Therapy for Congestive Heart Failure (Biventricular Pacing) (Guideline #5 Cardiac Resynchronization Therapy for Congestive Heart Failure).