## Coverage Summary

### Cardiac Pacemakers and Defibrillators

<table>
<thead>
<tr>
<th>Policy Number:</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date: 02/14/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 10/17/2017</td>
</tr>
</tbody>
</table>

**Related Medicare Advantage Policy Guidelines:**

- Anesthesia in Cardiac Pacemaker (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)

---

**INDEX TO COVERAGE SUMMARY**

I. COVERAGE

1. Cardiac Pacemakers (single-chamber or dual chamber)
2. Leadless Pacemakers
3. Cardiac Pacemaker Monitoring
4. Implantable Automatic Defibrillators
5. Subcutaneous Implantable Automatic Defibrillators
6. Automatic External Defibrillators
7. Anesthesia for Cardiac Pacemaker Surgery
8. Intraoperative Ventricular Mapping
9. External Counterpulsation (ECP) Therapy

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

---

### Coverage Statement

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
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 May 2, 2017)
   - *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 May 2, 2017)
   - *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 May 2, 2017)

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 October 10, 2017)
   
   
   Also see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.
   
   Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. These LCDs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx (Accessed October 10, 2017)

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 May 2, 2017)

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 May 2, 2017)

4. Implantable Automatic Defibrillators
Implantable automatic defibrillators are covered when criteria are met.
   • For the complete detailed coverage criteria, refer to the NCD for Implantable Automatic Defibrillators (20.4). (Accessed May 2, 2017)
   • For claims processing instructions, refer to the Medicare Claims Processing Manual, Chapter 32, §270.1 - Coding Requirements for Implantable Automatic Defibrillators. (Accessed May 2, 2017)

Notes:
   • All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR §405.201) and the CMS routine clinical trials policy (NCD §310.1)
   • ICD Registry:
      o Medicare requires patients receiving a defibrillator for the primary prevention of sudden cardiac arrest be enrolled in a qualifying data collection system.
      o As described in the NCD, indications for the primary prevention of sudden cardiac arrest require that data be reported on patients receiving ICDs. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals will need to
transitional to the ACC-NCDR ICD Registry by April 2006.


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 Articles do not exist at this time. (Accessed May 2, 2017)

**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 31832, as these codes are included in the NCD and CMS Medicare Claims Processing Manual.

6. **Automatic External Defibrillators**
   - Medicare does not have a National Coverage Determination (NCD) for automatic external defibrillators.
   - Local Coverage Determinations (LCDs) for automatic external defibrillators for all 50 states exist and compliance with these policies is required where applicable. All 4 DME MAC LCDs 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 May 2, 2017

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 May 2, 2017)

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 May 2, 2017)

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 May 2, 2017)*

**II. DEFINITIONS**

**External Counterpulsation (ECP):** Commonly referred to as enhanced external counterpulsation, is
a noninvasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force. 

**NCD for External Counterpulsation Therapy for Severe Angina (20.20)** (Accessed May 2, 2017)

**Implantable Automatic Defibrillator:** An electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. 

**NCD for Implantable Automatic Defibrillators (20.4)** (Accessed May 2, 2017)

**Intraoperative Ventricular Mapping:** The technique of recording cardiac electrical activity directly from the heart. The recording sites are usually identified from an anatomical grid and may consist of epicardial, intramural, and endocardial sites. A probe with electrodes is used to explore these surfaces and generate a map that displays the sequence of electrical activation. This information is used by the surgeon to locate precisely the site of an operative intervention. 


### III. REFERENCES

See above

### IV. REVISION HISTORY

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 ICD Registry.

01/18/2011 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).