Cardiac Procedures: Pacemakers, Defibrillators and Pulmonary Artery Pressure Measurements

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Instructions for Use

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Coverage Guidelines

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 Coverage Summary titled Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotic (Non-Foot Orthotics) and Medical Supplies Grid.

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, refer to the NCD for Cardiac Pacemaker (20.8).
- For dates of services on or after August 13, 2013, Refer to the NCD for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (20.8.3).
- For services for post-implant follow-up and evaluation of implanted cardiac pacemakers; refer to the NCD for Cardiac Pacemaker Evaluation Services (20.8.1).

(Accessed May 6, 2021)

Leadless Pacemakers (CPT Codes 33274 and 33275)

On January 18, 2017, the Centers for Medicare and 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 May 6, 2021)

Approved CED studies are posted on the CMS Coverage with Evidence Development webpage at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. (Accessed May 6, 2021)

Also refer to the Coverage Summary titled Experimental Procedures and Items, Investigational Devices and Clinical Trials.

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These policies are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx?redirect=Y&from=Overview. (Accessed May, 6, 2021)

Pulmonary Artery Pressure Measurements (CardioMEMS™ HF System) (CPT codes 33289, 93264 and C2624)

Medicare does not have a National Coverage Determination (NCD) for Pulmonary Artery Pressure Measurements (CardioMEMS™ HF System). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

CardioMEMS™ HF System is a Category B IDE device. Refer to the Coverage Summary titled Experimental Procedures and Items, Investigational Devices and Clinical Trials for coverage information on Category B IDE devices.

Refer to the CMS Approved IDE Studies information website for CardioMEMS™ HF System/Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) at https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies-Items/G170258-NCT03387813.html. (Accessed May 6, 2021)

Cardiac Pacemaker Monitoring

Self-Contained Pacemaker Monitors

Self-contained pacemaker monitors may be covered when prescribed by the treating physician with a cardiac pacemaker.

- 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.
- 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.

Refer to the NCD for Self-Contained Pacemaker Monitors (20.8.2). (Accessed May 6, 2021)

Trans-Telephonic Cardiac Pacemaker Monitoring

- Limited to lithium battery powered pacemakers
- Transtelephonic cardiac monitoring may be done by:
  - Member's physician
  - Outside entity requires an annually renewed physician's prescription and may include:
    - Commercial monitoring service
    - Hospital outpatient department
    - Pacemaker clinic
- Frequency of monitoring
  - Responsibility of member's physician to determine frequency
- In order for trans-telephonic cardiac monitoring services to be covered, the services must consist of the following:
  - Minimum 30 second readable strip of the pacemaker in the free running mode
  - Unless contraindicated, a minimum 30 second readable strip of the pacemaker in the magnetic mode

- Minimum 30 seconds of readable ECG/EKG strip

Refer to the NCD for Transtelephonic Monitoring of Cardiac Pacemakers (20.8.1.1). (Accessed May 6, 2021)

Implantable Cardioverter Defibrillators (ICDs)

An ICD is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias.

Effective for services performed on or after February 15, 2018, CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary when criteria are met.

Refer to the NCD for Implantable Automatic Defibrillators (20.4). (Accessed May 6, 2021)

Subcutaneous Implantable Automatic Defibrillators (CPT codes 33270, 33271, 33273, 93260, 93261 and 93644)

Subcutaneous implantable automatic defibrillators are covered when criteria are met. Refer to the NCD for Implantable Automatic Defibrillators (20.4). (Accessed May 6, 2021)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These policies are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. (Accessed May, 6, 2021)

Automatic External Defibrillators

Medicare does not have a National Coverage Determination (NCD) for automatic external defibrillators. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for all states/territories 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 LCD/LCA for Automatic External Defibrillators (L33690). (Accessed May 6, 2021)

Anesthesia for Cardiac Pacemaker Surgery

Anesthesia for cardiac pacemaker surgery is covered when reasonable and necessary. Refer to the NCD for Anesthesia in Cardiac Pacemaker Surgery (10.6). (Accessed May 6, 2021)

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.

Refer to the NCD for Intraoperative Ventricular Mapping (20.11). (Accessed May 6, 2021)

External Counterpulsation (ECP) Therapy

External counterpulsation (ECP) therapy for severe angina is covered when criteria are met.

Refer to the NCD for External Counterpulsation Therapy for Severe Angina (20.20). (Accessed May 6, 2021)

Policy History/Revision Information

Date	Summary of Changes
05/18/2021	• Routine review; no change to coverage guidelines

Date	Summary of Changes
	• Archived previous policy version MCS012.01

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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.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).