Cardiac Procedures: Pacemakers, Pulmonary Artery Pressure Measurements, Ventricular Assistive Devices, Valve Repair, and Valve Replacements

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Instructions for Use

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Related Policies
None

Coverage Guidelines

Cardiac pacemakers, internal and external pacemakers are covered when Medicare coverage criteria are met.

Note: The guidelines in this Coverage Summary are for specific procedures/medications only. For procedures/medications not addressed in this Coverage Summary, refer to the Medicare Coverage Database to search for applicable coverage policies (National Coverage Determinations, Local Coverage Determinations and Local Coverage Articles).

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, Orthotics (Non-Foot Orthotics), Nutritional Therapy, 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 Pacemakers (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 24, 2023)

Leadless Pacemakers (CPT Codes 33274 and 33275)

Effective January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development CED.

CMS covers leadless pacemakers when procedures are performed in Food and Drug Administration (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).

Approved CED studies are posted on the CMS Coverage with Evidence Development webpage at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers.

Also refer to the Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED). (Accessed August 4, 2023)

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 24, 2023)

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.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Omnibus Codes.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed August 23, 2023)

Valve Repairs and Replacements

Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CPT Code 33340)

Medicare covers percutaneous left atrial appendage closure (LAAC) for non-valvular atrial fibrillation (NVAF) through coverage with evidence development CED when coverage criteria are met.
- Refer to the NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34).
- All Medicare approved registries will be listed on the CED website located at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html.

For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
(Accessed May 23, 2023)

Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (CPT Codes 0345T, 33418, and 33419)

Medicare covers transcatheter edge-to-edge repair (TEER) for mitral valve regurgitation under coverage with evidence development CED.
- For coverage requirements and criteria, refer to the NCD for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33).
- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

- The list of Medicare approved clinical trials is available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR.html.
- For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).

(Accessed May 23, 2023)

Transcatheter Aortic Valve Replacement (TAVR) (CPT Codes 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, and 33369)

Medicare covers transcatheter aortic valve replacement (TAVR) under coverage with evidence development CED when criteria are met.

- Refer to the National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32).
- CMS considers TAVR as Category B devices and UnitedHealthcare MA plan is responsible for coverage of these devices when criteria are met. Refer to the Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
- The list TAVR Medicare approved clinical trials is available at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.
- To view the list of current Transcatheter Valve Therapy (TVT) Registry participants, go to https://www.ncdr.com/TVT/Private/Resources/ParticipantDirectory.aspx or contact the TVT Registry Service Center at (800) 257-4737. (Accessed May 23, 2023)

Transcatheter Pulmonary Heart Valve Replacement (CPT Code 33477)

Medicare does not have an NCD for transcatheter pulmonary heart valve replacement. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Transcatheter Heart Valve Procedures.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed August 21, 2023)

Ventricular Assist Devices (CPT Codes 33979, 33980, 33982, and 33983)

Ventricular assist device (VAD) and left ventricular assist device (LVAD) may be covered for the following indications:

Post-Cardiotomy

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

Left Ventricular Assist Devices (LVADS)

Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- Are inotrope dependent; **or**
- Have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
  - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
  - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Facility Criteria

Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities, must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A):

Beneficiaries receiving a VADs must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular VADs as BTT or DT over the course of the previous 36 months with activity in the last year
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant
- A VAD program coordinator
- A social worker
- A palliative care specialist

Facilities must be credentialed by an organization approved by CMS.

Note: A list of facilities eligible for Medicare reimbursement for destination therapy VADs is available at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html. (Accessed May 23, 2023)

Non-Covered Indications for VADs

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) for VADs in these situations will be made by local Medicare Administrative Contractors (MACs) within their respective jurisdictions.

Refer to the NCD for Ventricular Assist Devices (20.9.1). (Accessed May 23, 2023)

Policy History/Revision Information

Date	Summary of Changes
04/01/2024	**Coverage Guidelines** • Updated reference link to reflect title change for *Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid*
02/14/2024	**Coverage Guidelines** ***Ventricular Assist Devices (CPT Codes 33979, 33980, 33982, and 33983)*** • Added list of applicable CPT codes to service heading **Supporting Information** • Archived previous policy version MCS012.08

Instructions for Use

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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.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.