Ventricular Assist Device (VAD)

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Instructions for Use

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Related Medicare Advantage Policy Guidelines

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Coverage Guidelines

Ventricular assist devices are covered when Medicare coverage criteria are met.

COVID-19 Public Health Emergency Waivers and Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain services related to percutaneous left atrial appendage closure, transcatheter aortic valve replacement, transcatheter mitral valve replacement and ventricular assist devices.

For a comprehensive list of coronavirus waivers and flexibilities, refer to https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers. (Accessed October 4, 2021)

Ventricular Assist Devices

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 October 4, 2021)

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 October 4, 2021)

Replacements

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

- A change in the physiological condition of the patient;
- An irreparable change in the condition of the device, or in a part of the device; or
- The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that that provided a 5-year or other replacement rule with regard to prosthetic devices.

Refer to the Medicare Benefit Policy Manual, Chapter 15, §120 – Prosthetic Devices. (Accessed October 4, 2021)

Note: All transplant procedures including for UnitedHealthcare MedicareComplete members must be performed in a UnitedHealthcare MedicareComplete Preferred Transplant Network facility.
This does not apply to UnitedHealthcare MedicareDirect members.

Policy History/Revision Information

Date	Summary of Changes
10/19/2021	• Routine review; no change to coverage guidelines • Archived previous policy version MCS100.02

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

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).