Coverage Summary

Ventricular Assist Device (VAD) and Artificial Heart

Policy Number: V-003 Products: UnitedHealthcare Medicare Advantage Plans

Original Approval Date: 02/14/2008

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee

Last Review Date: 01/19/2021

Related Medicare Advantage Policy Guidelines:

- Artificial Hearts and Related Devices (NCD 20.9)
- Percutaneous Ventricular Assist Device
- Routine Costs in Clinical Trials (NCD 310.1)
- Ventricular Assist Devices (NCD 20.9.1)

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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.

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).

INDEX TO COVERAGE SUMMARY

I. COVERAGE
   1. Ventricular Assist Devices (VADs)
   2. Artificial Hearts
   3. Replacements

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

I. COVERAGE

Coverage Statement: Ventricular assist devices are covered when Medicare coverage criteria are met.

COVID-19 Public Health Emergency Waivers & 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 details, see the following Coronavirus Waivers/Flexibilities: Physicians and Other Practitioners (PDF).


(Accessed October 12, 2020)
Guidelines/Notes:

1. **Ventricular Assist Devices**
   a. Ventricular assist device (VAD) and left ventricular assist device (LVAD) may be covered for the following indications:
      1) **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.
      2) **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/MedicareApprovedFacilities/VAD-Destination-Therapy-Facilities.html](http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/VAD-Destination-Therapy-Facilities.html). (Accessed October 13, 2020)

3) **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.

4) **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.


Also see the [CMS Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N)](http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/VAD-Destination-Therapy-Facilities.html) dated December 1, 2020. (Accessed December 9, 2020)

2. **Artificial Hearts**

Effective December 1, 2020, The Centers for Medicare & Medicaid Services (CMS) is removing the NCD at § 20.9, ending coverage with evidence development for artificial hearts and permitting Medicare coverage determinations for artificial hearts to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act.


3. **Replacements**

a. 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:
   1) A change in the physiological condition of the patient;
   2) An irreparable change in the condition of the device, or in a part of the device; or
   3) 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.


**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.

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**II. DEFINITIONS**

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**III. REFERENCES**

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**IV. REVISION HISTORY**

01/19/2021  **Guideline 1 (Ventricular Assist Devices)**
- Added reference link to the Centers for Medicare & Medicaid Services (CMS) Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N)

**Guideline 1.a. [Ventricular Assist Device (VAD) and Left Ventricular Assist Device (LVAD)]**
- Replaced language indicating “ventricular assist device (VAD) and left ventricular assist device (LVAD) are covered for the [listed] indications” with “ventricular assist device (VAD) and left ventricular assist device (LVAD) may be covered for the [listed] indications”

**Guideline 1.a.2 [Left Ventricular Assist Devices (LVADs)]**
- Revised coverage guidelines for VADs as bridge-to-transplant and destination therapy to indicate 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

- Replaced language indicating “beneficiaries receiving VADs for destination therapy (DT) must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience” with “beneficiaries receiving a VAD must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience”
Guideline 2 (Artificial Hearts)

- Revised coverage guidelines to indicate:
  - Effective Dec. 1, 2020, CMS is removing the National Coverage Determination (NCD) at § 20.9, ending coverage with evidence development for artificial hearts and permitting Medicare coverage determinations for artificial hearts to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act
  - Added reference link to the CMS Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N)

Definitions

- Removed definition of:
  - Artificial Heart
  - Ventricular Assist Device (VAD) or Left Ventricular Assist Device (LVAD)