Coverage Summary

Ventricular Assist Device (VAD) and Artificial Heart

<table>
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<th>Policy Number: V-003</th>
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<tr>
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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.

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I. COVERAGE

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

Guidelines/Notes:
1. Ventricular Assist Devices
   a. Ventricular assist device (VAD) and left ventricular assist device (LVAD) are 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) VADs as Bridge-to-Transplant
         The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the
FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

- The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.
- The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

3) **VADs as Destination Therapy**

Destination therapy is for patients that require mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose.

**Patient Selection**

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant and meet all of the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
- Have a left ventricular ejection fraction (LVEF) < 25%, and,
- Have demonstrated functional limitation with a peak oxygen consumption of $\leq 14 \text{ ml/kg/min}$ unless balloon pump- or inotrope-dependent or physically unable to perform the test.

**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 VADs for DT 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.


4) **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.

5) **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.


2. **Artificial Hearts**

a. **Artificial Hearts as Bridge-to-Transplant**

An artificial heart for bridge-to-transplantation (BTT) is covered when performed under coverage with evidence development (CED) when a clinical study meets all of the Medicare criteria.

b. **Artificial Hearts as Destination Therapy**

An artificial heart as destination therapy (DT) is covered when performed under (CED) when a clinical study meets all of the criteria.

c. **Non-Covered Indications**

All other indications for the use of VADs or artificial hearts 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 NCD Manual.

d. **Other**

Clinical study criteria:

1) The study must be reviewed and approved by the Food and Drug Administration (FDA).
2) The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
3) The research study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

4) The research study does not unjustifiably duplicate existing studies.

5) The research study design is appropriate to answer the research question being asked in the study.

6) The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

7) The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated it also must be in compliance with 21 CFR Parts 50 and 56.

8) All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

9) The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with study participation (CSP) or CED coverage.

10) The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life and the patient has no other viable treatment options.

11) The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator as demonstrated by having a National Clinical Trial control number.

12) The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

13) The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

14) The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator of an artificial heart clinical study seeking Medicare payment should submit the following documentation to the Centers for Medicare & Medicaid Services (CMS) and should expect to be notified when the CMS review is complete:

- Complete study protocol (must be dated or identified with a version number);
• Protocol summary;
• Statement that the submitted protocol version has been agreed upon by the FDA;
• Statement that the above study standards are met;
• Statement that the study addresses at least one of the above questions related to artificial hearts;
• Complete contact information (phone number, email address, and mailing address); and,
• Clinicaltrials.gov registration number.

For criteria and detailed instructions, refer to the NCD for Artificial Hearts and Related Devices (20.9). (Accessed September 23, 2016)


For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

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 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.**

### II. DEFINITIONS

**Artificial Heart:** An artificial heart is a biventricular replacement device which requires removal of a substantial part of the native heart, including both ventricles. Removal of this device is not compatible with life, unless the patient has a heart transplant. NCD for Artificial Hearts and Related Devices (20.9) (Accessed September 23, 2016)

**Ventricular Assist Device (VAD) or Left Ventricular Assist Device (LVAD):** A device which is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood. Improvement in the performance of the native heart may allow the device to be removed. NCD for Ventricular Assist Devices (20.9.1) (Accessed September 23, 2016)
III. REFERENCES
See above

IV. REVISION HISTORY

10/18/2016  Annual review; no updates.
10/20/2015  Annual review; no updates.
04/21/2015  Guideline #2 (Artificial Hearts)
  • Updated the reference information to the list of Medicare approved clinical trials.
    Added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.
10/21/2014  Annual review with the following updates:
  • Guideline #1 (Ventricular Assist Devices) -Added reference link to the NCD for Ventricular Assist Devices (20.9.1)
  • Definitions - Updated the definition of Artificial Heart; added reference link to the NCD for Artificial Hearts and Related Devices (20.9)
02/18/2014  Coverage Summary updated to include the updates to the VAD-related National Coverage Determination (NCDs) 20.9.1, in accordance with the October 30, 2013 CMS Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00432R)
10/24/2013  Annual review; updated Guidelines # 3 Replacements to include applicable guidelines based on the Medicare Benefit Policy Manual Chapter 15 Medical and Other Health Services; §120 Prosthetic Devices
10/31/2012  Annual review; updated to include detailed coverage language based on the NCD for Artificial Hearts and Related Devices (20.9)
08/29/2011  Annual review; no updates
12/20/2010  Updated link to the NCD for Artificial Hearts and Related Devices (20.9); CMS updated VADs as Destination Therapy patient selection criteria effective 11/9/2010