Overview

Ventricular assist devices (VADs) or left ventricular assist devices (LVADs) are mechanical blood pumps that are surgically attached to one or both intact ventricles of a damaged or weakened native heart to assist in pumping blood. The heart remains intact with VADs with the possibility for the native heart to recover and for removal of the device. Patients who may be candidates for LVAD implant undergo extensive clinical testing to ensure an adequate severity of heart failure but acceptable severity of comorbidities.

Guidelines

Nationally Covered 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.

Advanced Heart Failure

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.

Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with 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 informed decision making. 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 assist devices 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 placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

**Facility Criteria**

Facilities must be credentialed by an organization approved by CMS. The process for organizations to apply for CMS approval to be designated as a credentialing organization for LVAD facilities is posted on our web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: [http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html](http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html)

**Nationally Non-Covered Indications**

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) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

**Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33979</td>
<td>Insertion of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33980</td>
<td>Removal of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33982</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass</td>
</tr>
</tbody>
</table>
CPT Code | Description
--- | ---
33983 | Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass

ICD Procedure Code | Description
--- | ---
02HA0QZ | Insertion of Implantable Heart Assist System into Heart, Open Approach
02PA0QZ | Removal of Implantable Heart Assist System from Heart, Open Approach
02WA0QZ | Revision of Implantable Heart Assist System in Heart, Open Approach

References

CMS National Coverage Determinations (NCDs)
NCD 20.9.1 Ventricular Assist Devices
Related NCDs: NCD 310.1 Routine Costs in Clinical Trials

CMS Claims Processing Manual
Chapter 32; § 320.3 Ventricular Assist Devices

CMS Transmittal(s)
Transmittal 2427, Change Request 11491, Dated 02/04/2020 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--April 2020 Update)
Transmittal 10837, Change Request 12290, Dated 06/11/2021 (National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs))

MLN Matters
Article MM12290, National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs)

UnitedHealthcare Commercial Policy
Total Artificial Heart and Ventricular Assist Devices

Other(s)
CMS Process for VAD Approval of Credentialing Organizations, CMS Website
Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N)
VAD Destination Therapy Facilities, CMS Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy Summary</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/2021</td>
<td><strong>Overview</strong></td>
<td>Revised language to indicate:</td>
</tr>
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<td></td>
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</table>

#### Nationally Covered Indications

**Bridge-to-Transplant (removed)**
- Removed content/language addressing ventricular assist devices (VADs) used for bridge to transplant

**Destination Therapy (DT) (removed)**
- Removed content/language addressing VADs used for destination therapy

**Patient Selection (removed)**
- Removed content/language addressing VADs for patients with chronic end-stage heart failure who are not candidates for heart transplantation at the time of VAD implant

**Advanced Heart Failure (new to policy)**
- Added language 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:
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  - Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with 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 informed decision making; 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 assist devices 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 placement of a VAD
    - A VAD program coordinator
    - A social worker
    - A palliative care specialist

#### Facility Criteria
- Revised language to indicate:
  - Facilities must be credentialed by an organization approved by CMS
  - The process for organizations to apply for CMS approval to be designated as a credentialing organization for LVAD facilities is posted on our [CMS] website along with a list of approved
Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.
Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.