VENTRICULAR ASSIST DEVICES (NCD 20.9.1)

Guideline Number: MPG343.04

Approval Date: October 10, 2018

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POLICY SUMMARY

Overview
A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

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.

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 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 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 transplant center under which the patient is listed prior to implantation of the VAD.

Destination Therapy (DT)
Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT 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 the following conditions:

• Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 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 < 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria
Facilities must be in compliance with the following criteria as determined by a credentialing organization. New facilities must meet the following criteria as a condition of coverage of this procedure as DT:
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 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.

**Note:** Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

**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 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>
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<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>
<tr>
<td>33983</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass</td>
</tr>
</tbody>
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*Note to the right: CPT® is a registered trademark of the American Medical Association*

<table>
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<tr>
<th>ICD-10 Procedure Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>02HA0QZ</td>
<td>Insertion of Implantable Heart Assist System into Heart, Open Approach</td>
</tr>
<tr>
<td>02PA0QZ</td>
<td>Removal of Implantable Heart Assist System from Heart, Open Approach</td>
</tr>
<tr>
<td>02WA0QZ</td>
<td>Revision of Implantable Heart Assist System in Heart, Open Approach</td>
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**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 LCDs, NCDs, 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.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 20.9.1 Ventricular Assist Devices
Related NCDs: NCD 20.9 Artificial Hearts and Related Devices, NCD 310.1 Routine Costs in Clinical Trials

CMS Benefit Policy Manual
Chapter 15; § 232 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

CMS Claims Processing Manual
Chapter 32; § 140 Cardiac Rehabilitation Programs, Intensive Cardiac Rehabilitation Programs, and Pulmonary Rehabilitation Programs, § 320.3 Ventricular Assist Devices

CMS Transmittals
Transmittal 1975, Change Request 10318, Dated 11/09/2017 (ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs))

MLN Matters
Article MM7220, Ventricular Assist Devices (VADs) as Destination Therapy
Article MM8803, VADs for Bridge-to-Transplant and Destination Therapy
Article SE0424, Clarification for Billing Left Ventricular Assist Devices

Others
CMS Process for VAD Approval of Credentialing Organizations, CMS Website
FDA Investigational Device Exemption (IDE), FDA Website
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>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>10/10/2018</td>
<td>• Annual MAPG Committee presentation and approval</td>
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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.

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*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.