Ventricular Assist Device, Total Artificial Heart

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Medicare Advantage Medical Coverage Policy

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Disclaimer
The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member’s coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Cardioverter Defibrillators/Cardiac Resynchronization Therapy

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.
## Description

**Ventricular Assist Device**

A ventricular assist device (VAD) is a mechanical pump that compensates for the diminished ability of a weakened heart, by assisting or replacing the function of the left or right ventricle. A left VAD (the most commonly used) provides blood flow throughout the body while the right VAD supports the pulmonary (lung) circulation. VADs may be utilized for an individual suffering from reversible cardiac dysfunction, to support an individual who is awaiting heart transplantation or to provide permanent circulatory support with end-stage heart failure (HF) in those who are not a candidate for transplantation (known as destination therapy).

There are many VADs available for use. Important characteristics of these systems include: location of the pumping chamber, the specific ventricles that are supported, the pumping mechanism and how long support (temporary or long-term) is indicated. Typically, short-term devices are extracorporeal (located outside the body) and long-term use are implantable systems. Generally these devices are placed via a sternotomy; however, some have received US Food & Drug Administration (FDA) approval for placement via a thoracotomy (eg, HeartMate 3).

FDA-approved VADs include, but may not be limited to, the following:

- **Bridge to transplant**: CentriMag Circulatory Support System, HeartMate II LVAD, HeartMate 3 LVAD.

<table>
<thead>
<tr>
<th>NCD</th>
<th>Ventricular Assist Devices Artificial Hearts and Related Devices</th>
<th>20.9.1 65-15</th>
<th>Administrative Contractors (MACs)</th>
<th>CA, HI, NV, American Samoa, Guam, Northern Mariana Islands</th>
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</thead>
<tbody>
<tr>
<td>LCA</td>
<td>Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices</td>
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<td>JE - Noridian Healthcare Solutions, LLC</td>
<td>AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY</td>
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<td>A53986</td>
<td>JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)</td>
<td>NC, SC, VA, WV</td>
</tr>
</tbody>
</table>
• Destination therapy: HeartMate II LVAD, HeartMate 3 LVAD.

• Short-term bridge to recovery: CentriMag Circulatory Support System, HeartMate 3 LVAD.

The HeartWare HVAD has been voluntarily recalled by the manufacturer due to neurological complications with the device and is no longer being sold/distributed.81

Percutaneous ventricular assist devices (pVADs) differ from other types of VADs as they can be placed via cardiac catheterization without the need for open-chest surgery, which avoids potential difficulties in crossing the aortic valve.

pVADs are utilized for short-term bridge to recovery (eg, less than or equal to 4 hours for Impella 2.5 and Impella CP with SmartAssist, less than or equal to 6 hours for Impella 5.0/LD, LifeSPARC system and TandemHeart and up to 14 days for the Impella 5.5 with SmartAssist).77,84 Examples of pVADs include, but may not be limited to:

• Aortix Percutaneous Mechanical Circulatory Support (pMCS) (Refer to Coverage Limitations section)
• Impella 2.5 System
• Impella 5.0 (LP/LD)
• Impella 5.5 with SmartAssist*
• Impella CP with SmartAssist*
• LifeSPARC system
• TandemHeart

*SmartAssist technology is designed to provide physicians with weaning algorithms as well as additional data such as left ventricular (LV) pressure, end diastolic pressure and cardiac output with the intent of optimizing survival and recovery. The data can be accessed via an online database.

The CentriMag Circulatory Support System is indicated for temporary circulatory support for up to 30 days for one or both sides of the heart to treat postcardiotomy individuals who fail to wean from cardiopulmonary bypass. This provides a bridge to decision when it is unclear whether the individual’s heart will recover or whether the individual will need alternative, longer-term therapy.83

The Impella RP System is indicated for providing temporary right ventricular support for up to 14 days in individuals with a body surface area ≥1.5 m², who develop acute right heart failure or decompensation for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.99 In addition, the Impella RP Flex is implanted via the internal jugular (IJ) vein, which purportedly enables patient mobility, and has dual-sensor technology designed to optimize patient management.

Total Artificial Heart
A total artificial heart (TAH) is a device that replaces the two lower chambers of the heart and is available to individuals with end-stage heart failure.
The SynCardia temporary TAH-t is intended for an individual who is on a heart transplant list and are so critically ill that death is imminent without use of this as a bridge until a heart transplant is available. The SynCardia TAH-t is an implantable device that is driven by compressed air and replaces the function of the ventricles.

It attaches to the individual’s atria after the damaged ventricles are removed. Each ventricle of the TAH is connected to a driveline that is tunneled through the chest wall and attached to an external bedside console that supplies pulses of pneumatic pressure to the left and right drivelines, which are connected to the air chambers of their respected ventricles. These air pulses distend the diaphragms ejecting blood from the left ventricle and right ventricle synchronously to the systemic and pulmonary circulation.44 The SynCardia 70cc TAH-t is intended to support individuals with a body surface area (BSA) greater than or equal to 1.7m². The 50cc TAH-t is also available, which is designed for an individual that is smaller in stature with a BSA less than or equal to 1.85m².

Traditionally, artificial heart technology has used large, hospital-based pneumatic driver systems, which require an individual to be hospitalized while awaiting a donor heart. However, the Freedom portable driver has been developed, which purportedly enables a stable individual to be discharged from the hospital to await a suitable donor heart at home.

Permanently implantable aortic counterpulsation ventricular assist devices as a bridge to recovery are being investigated using surgically implanted counterpulsation devices that are placed in or around the aorta. This treatment is based on the scientific principle of an intraaortic balloon pump (IABP) that provides counterpulsation, which is theorized to stimulate the work and reduce the afterload of the left ventricle. There are currently no FDA-approved continuous internal pulsation devices. Examples of devices in development or in clinical trials include, but may not be limited to: CardioVAD, C-pulse heart assist system, NuPulse iVAS, PULVAD device and the Symphony counterpulsation device.52

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for Ventricular Assist Devices for Bridge to Transplant and Destination Therapy.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Percutaneous insertion of an FDA-approved endovascular cardiac assist device (pVAD), when external counterpulsation (IABP) is not expected to be sufficient, will be considered medically reasonable and necessary when the following indications are met:
• Cardiogenic shock
• Severe decompensated heart failure with threatening multi-organ failure
• Complications/disturbance of the circulatory system intra-operatively or postoperatively

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 the CMS site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: [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)

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

### Coverage Limitations

US Government Publishing Office. **Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage**

The following tests will not be considered medically necessary and reasonable: ¹⁷:

- pVAD
- TAH
- VAD

From 20.9.1: C. 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. ¹⁷

The following **cardiac support devices/systems** will not be considered medically reasonable and necessary:

- Aortix pMCS device
- Permanently implantable aortic counterpulsation ventricular assist device
- SynCardia freedom driver system

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies
examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**Summary of Evidence**

**Aortix pMCS Device**
There is no published evidence evaluating the use of Aortix for acute decompensated heart failure (ADHF). Additional larger clinical studies that evaluate its use in patients with ADHF are necessary to determine its safety, effectiveness, and clinical utility in treating ADHF and cardiorenal syndrome. Aortix is also under investigation to prevent renal complications in patients undergoing cardiovascular surgery who are at increased risk of acute kidney injury (AKI); the first patients were enrolled and treated in late February 2023. Additionally, there are no position statements or guidelines addressing the use of the Aortix device.

**Permanently Implantable Aortic Counterpulsation Ventricular Assist Device**
Evidence regarding counterpulsation devices were recorded in the World Journal of Transplantation as urgently requiring additional experimental and clinical studies to better characterize their role in HF.

**Syncardia Freedom Driver System**
Very little published evidence was available regarding the use of portable drivers with the TAH.

**Coding Information**
Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<th>CPT® Code(s)</th>
<th>Description</th>
<th>Comments</th>
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<td>33927</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy</td>
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<td>Removal and replacement of total replacement heart system (artificial heart)</td>
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<tr>
<td>33929</td>
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<tr>
<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
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<tr>
<td>33977</td>
<td>Removal of ventricular assist device; extracorporeal, single ventricle</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>33978</td>
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<td>33980</td>
<td>Removal of ventricular assist device, implantable intracorporeal, single ventricle</td>
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<td>33981</td>
<td>Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump</td>
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<td>33982</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass</td>
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<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass</td>
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<td>33990</td>
<td>Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only</td>
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<td>Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture</td>
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<td>Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion</td>
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<td>Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion</td>
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<td>33995</td>
<td>Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only</td>
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<tr>
<td>33997</td>
<td>Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion</td>
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<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
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<td>93750</td>
<td>Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report</td>
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<td>L8698</td>
<td>Miscellaneous component, supply or accessory for use with total artificial heart system</td>
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<td>Q0477</td>
<td>Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
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<td>Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type</td>
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<td>Driver for use with pneumatic ventricular assist device, replacement only</td>
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<td>Q0481</td>
<td>Microprocessor control unit for use with electric ventricular assist device, replacement only</td>
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<td>Q0482</td>
<td>Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only</td>
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<tr>
<td>Q0483</td>
<td>Monitor/display module for use with electric ventricular assist device, replacement only</td>
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<td>Q0484</td>
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<td>Monitor control cable for use with electric ventricular assist device, replacement only</td>
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<td>Q0486</td>
<td>Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only</td>
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<td>Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only</td>
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<td>Power pack base for use with electric/pneumatic ventricular assist device, replacement only</td>
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<td>Q0490</td>
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<td>Q0497</td>
<td>Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
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<td>Holster for use with electric or electric/pneumatic ventricular assist device, replacement only</td>
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<td>Q0499</td>
<td>Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only</td>
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<td>Q0502</td>
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<td>Battery for pneumatic ventricular assist device, replacement only, each</td>
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<td>Q0509</td>
<td>Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A</td>
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**References**


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**Appendix**

**New York Heart Association (NYHA) Functional Classification System**

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<thead>
<tr>
<th>Classification</th>
<th>Symptoms</th>
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<tbody>
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<td>Class I (asymptomatic)</td>
<td>No limitations on physical activity</td>
</tr>
<tr>
<td></td>
<td>Ordinary physical activity does not cause undue fatigue, palpitations or dyspnea (shortness of breath)</td>
</tr>
<tr>
<td>Class</td>
<td>Description</td>
</tr>
<tr>
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</tr>
</tbody>
</table>
| II (mild) | Slight limitations on physical activity  
Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea |
| III (moderate) | Marked limitations on physical activity  
Comfortable at rest, but less than ordinary activity causes fatigue, palpitations or dyspnea |
| IV (severe)  | Unable to carry out any physical activity without discomfort  
Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased |

**Change Summary**

- 01/01/2024 New Policy.