Ventricular Assist Device, Total Artificial Heart

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

Table of Contents

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.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories

			Administrative Contractors (MACs)	
NCD	Ventricular Assist Devices Artificial Hearts and Related Devices	20.9.1 65-15		
LCA	Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices	A52966	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices	A52967	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCA	Billing and Coding: Percutaneous Ventricular Assist Device	A53986	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV

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.[19] 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.**

- 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 m^2, 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 1.7m^2. 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 1.85m^2.

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/MedicareApprovedFacilitie/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.[33] 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.[52]

SynCardia Freedom Driver System
Very little published evidence was available regarding the use of portable drivers with the TAH.[44]

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.

CPT® Code(s)	Description	Comments
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy	
33928	Removal and replacement of total replacement heart system (artificial heart)	
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)	
33975	Insertion of ventricular assist device; extracorporeal, single ventricle	
33976	Insertion of ventricular assist device; extracorporeal, biventricular	
33977	Removal of ventricular assist device; extracorporeal, single ventricle	

33978	Removal of ventricular assist device; extracorporeal, biventricular	
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle	
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle	
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump	
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass	
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass	
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only	
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture	
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion	
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion	
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion	
33999	Unlisted procedure, cardiac surgery	
93750	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	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		

HCPCS Code(s)	Description	Comments
L8698	Miscellaneous component, supply or accessory for use with total artificial heart system	
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type	
Q0479	Power module for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0480	Driver for use with pneumatic ventricular assist device, replacement only	
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only	
Q0482	Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only	
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only	
Q0484	Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0485	Monitor control cable for use with electric ventricular assist device, replacement only	
Q0486	Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only	
Q0487	Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only	
Q0488	Power pack base for use with electric ventricular assist device, replacement only	
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only	
Q0490	Emergency power source for use with electric ventricular assist device, replacement only	
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only	
Q0492	Emergency power supply cable for use with electric ventricular assist device, replacement only	
Q0493	Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only	
Q0494	Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only	

Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0496	Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0499	Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only	
Q0500	Filters for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0502	Mobility cart for pneumatic ventricular assist device, replacement only	
Q0503	Battery for pneumatic ventricular assist device, replacement only, each	
Q0504	Power adapter for pneumatic ventricular assist device, replacement only, vehicle type	
Q0506	Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only	
Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device	
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device	
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A	

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Appendix

New York Heart Association (NYHA) Functional Classification System

Classification	Symptoms
Class I (asymptomatic)	No limitations on physical activity Ordinary physical activity does not cause undue fatigue, palpitations or dyspnea (shortness of breath)

Class II (mild)	Slight limitations on physical activity Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea
Class III (moderate)	Marked limitations on physical activity Comfortable at rest, but less than ordinary activity causes fatigue, palpitations or dyspnea
Class 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.