

# Ventricular Assist Device, Total Artificial Heart



Medicaid Medical Coverage Policy

Original Effective Date: 07/01/2025

Effective Date: 07/01/2025

Review Date: 07/01/2025

Policy Number: HUM-2234-000

Line of Business: Medicaid

States(s): VA

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## Description

For an individual experiencing decreased heart function, such as cardiogenic shock or advanced heart failure (HF) unmanageable with optimal medical and device-based therapies, mechanical circulatory support (MCS) from a ventricular assist device (VAD) or total artificial heart (TAH) may be a treatment option. These devices can be utilized short- or long-term, reduce the risk of death and improve quality of life.<sup>45,47</sup>

### Ventricular Assist Device

A VAD compensates for the diminished ability of a weakened heart, boosting the function of a deteriorating left or right ventricle, decreasing ventricular filling pressures and expanding perfusion. There are many VADs available for use and include important characteristics such as location of the pumping chamber, specific ventricles that are supported, pumping mechanism and how long support (short- or long-term) is indicated. Typically, short-term devices are extracorporeal (located outside the body) and long-term devices are implantable (located inside the body).<sup>19,45,47</sup>

- **Left VADs (LVADs)** support the left ventricle, distributing oxygenated blood to the aorta and throughout the body. LVADs can be used for temporary support until the heart regains function (bridge to recovery [BTR]), until time of heart transplantation (bridge to transplantation [BTT]) or as an alternative to transplantation (destination therapy [DT]) for an individual not eligible for transplant.<sup>9,24</sup>

- **Right VADs (RVADs)** support the right ventricle, distributing unoxygenated blood into the pulmonary artery to receive oxygenation in the lungs. Similar to LVADs, RVADs can be used for temporary support until the heart regains function (BTR), until time of heart transplantation (BTT) or as an alternative to transplantation (DT) for an individual not eligible for transplant.<sup>9,24</sup>
- **BiVADs** are a combination of both the LVAD and RVAD. The BiVAD supports both ventricles simultaneously, performing the function of both the LVAD and RVAD. Therefore, permitting total decompression of both ventricles and providing whole end-organ perfusion.<sup>33</sup>
- **Percutaneous VADs (pVADs)** differ from other types of VADs as they can be placed via cardiac catheterization without the need for open-chest surgery, avoiding potential difficulties crossing the aortic valve. pVADs are commonly used for cardiac support during high-risk percutaneous circulatory intervention procedures in an individual with severe left ventricular failure or cardiogenic shock associated with a myocardial infarction.<sup>2,20</sup>

### **Total Artificial Heart**

A TAH is a long-term or durable mechanical circulatory support device used to treat intractable, biventricular HF not amendable to treatment from a VAD. The TAH performs the same function as a VAD, but in contrast to the VAD supporting heart function, the TAH replaces the function of the native heart entirely. TAHs are used for long-term as a BTT or DT.<sup>25</sup>

## **Coverage Determination**

### **VADs - Bridge to Recovery (33975, 33979)**

Humana members may be eligible under the Plan for **VADs** as a bridge to recovery when the following criteria are met:

- FDA approved device and used in accordance with the FDA approved labeling instructions<sup>18</sup>; **AND**
- Individual has acute, but potentially reversible heart failure due to:
  - Acute myocarditis<sup>14</sup>; **OR**
  - Myocardial infarction<sup>14</sup>; **OR**
  - Peripartum cardiomyopathy<sup>13</sup>; **OR**
  - Post-cardiotomy and cannot be weaned from cardiopulmonary bypass<sup>18</sup>

### **Adult LVADs - Bridge to Heart Transplantation (33975, 33979)**

Humana members may be eligible under the Plan for **LVADs** as a bridge to transplant when the following criteria are met:

- FDA approved device and used in accordance with the FDA approved labeling instructions<sup>18</sup>; **AND**
- [New York Heart Association \(NYHA\) Class IV heart failure](#)<sup>19</sup>; **AND**

- Left ventricular ejection fraction (LVEF) less than or equal to 25%<sup>19</sup>;
- **AND either** of the following:
  - Inotrope dependent<sup>19</sup>; **OR**
  - Cardiac Index (CI) less than 2.2 L/min/m<sup>2</sup>, while not on inotropes<sup>19</sup>; **AND 1** of the following:
    - Is on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and failing to respond<sup>18</sup>; **OR**
    - Advanced heart failure for at least 14 days and dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days<sup>18</sup>

**RVADs (33975, 33979)**

Humana members may be eligible under the Plan for **RVADs** when the following criteria are met:

- FDA approved device and used in accordance with the FDA labeling instructions<sup>48</sup>; **AND**
- Adult or pediatric individual with a BSA greater than or equal to 1.5m<sup>48</sup>; **AND**
- Individual who develops acute right heart failure or decompensation for less than 48 hours following<sup>48</sup>:
  - Heart transplant; **OR**
  - LVAD implantation; **OR**
  - Myocardial infarction; **OR**
  - Open heart surgery; **AND**
- Individual is agreeable to be treated with heparin or a comparable alternative<sup>50</sup>; **AND**
- May be utilized for a maximum period of 14 days<sup>48</sup>

**BiVADs (33976)**

Humana members may be eligible under the Plan for **BiVADs** when the following criteria are met:

- FDA approved device and used in accordance with the FDA labeling instructions<sup>50</sup>; **AND**
- Post-cardiotomy and cannot be weaned from cardiopulmonary bypass<sup>50</sup>; **AND**
- Individual is agreeable to be treated with Heparin or a comparable alternative<sup>50</sup>; **AND**
- May be utilized for a maximum period of 30 days<sup>50</sup>

**Pediatric VAD - Bridge to Heart Transplantation (33975, 33979)**

Humana members may be eligible under the Plan for an FDA approved **pediatric VAD** (including humanitarian device exemptions [HDE]) as a bridge to transplant when the device is FDA approved and is used according to the FDA approved indications.<sup>36,51</sup>

**TOTAL ARTIFICIAL HEART (33927, L8698)**

Humana members may be eligible under the Plan for the **TAH** when the device is FDA approved and is used according to the FDA approved indications.<sup>49</sup>

**TAH- removal and/or replacement (33928 and 33929)**

Humana members may be eligible under the Plan for removal and/or replacement of a TAH when the following requirements are met:

- Initial TAH implantation requirements are met<sup>49</sup>; **AND**
- Adverse complication resulting from the TAH. Examples of such a complication may include, but are not limited to<sup>37,49</sup>:
  - Anastomosis break
  - Bleeding
  - Device malfunction
  - Infection
  - Thrombosis; **OR**
- Human heart transplantation<sup>49</sup>

**Coverage Limitations**

Humana members may **NOT** be eligible under the Plan for **VADs or TAH** for any indications other than those listed above.

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**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	
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle	
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	
ICD-10-PCS Code(s)	Description	Comments
No code(s) identified		

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**Appendix**

**Appendix A**

**New York Heart Association (NYHA) Functional Classification System<sup>32</sup>**

Classification	Symptoms
Class I (asymptomatic)	<ul style="list-style-type: none"> <li>• No limitations on physical activity</li> <li>• Ordinary physical activity does not cause undue fatigue, palpitations or dyspnea (shortness of breath)</li> </ul>
Class II (mild)	<ul style="list-style-type: none"> <li>• Slight limitations on physical activity</li> <li>• Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea</li> </ul>
Class III (moderate)	<ul style="list-style-type: none"> <li>• Marked limitations on physical activity</li> <li>• Comfortable at rest, but less than ordinary activity causes fatigue, palpitations or dyspnea</li> </ul>
Class IV (severe)	<ul style="list-style-type: none"> <li>• Unable to carry out any physical activity without discomfort</li> <li>• Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased</li> </ul>

**Change Summary**

07/01/2025 New Policy.