

## Medica Coverage Policy



<b>Policy Name:</b>	<b>Mechanical Circulatory Support Devices</b>
<b>Effective Date:</b>	<b>1/15/2024</b>

### Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

### Coverage Policy

**Note:** This policy is no longer scheduled for routine review of the scientific literature.

#### **Total Artificial Heart**

An FDA approved total artificial heart (TAH) used as a bridge to heart transplantation in individuals with biventricular heart failure who have failed optimal medical therapy, are at imminent risk of death and are currently listed as a heart transplant candidate is **COVERED**.

Non-FDA approved TAHs and/or the use of a TAH for all other indications, including destination therapy, is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

#### **Ventricular Assist Devices**

Ventricular assist devices (VAD), including percutaneous ventricular assist devices are **COVERED** when a FDA-approved device is used for bridge to transplantation, bridge to recovery, bridge to decision, and destination therapy.

**Note for both TAH & VAD:** This determination does not apply to devices that have been granted a humanitarian device exemption (HDE) by the FDA. Medica considers an FDA-approved humanitarian device exemption (HDE) device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>

**Note:** For both procedures, please refer to related Medica Utilization Management policies, *Heart Transplantation (Adult and Pediatric) III-TRA.12* and *Heart/Lung Transplantation III-TRA.08*.

### Description

#### **Total Artificial Heart**

The SynCardia temporary total artificial heart (TAH) is an implantable, pneumatic, biventricular support device that

serves as a total replacement for both ventricles of the failing heart. The TAH device is used as a bridge to heart transplantation for patients with biventricular heart failure, who have not responded to other treatments, who are at imminent risk of death and who are currently listed as a heart transplantation candidate.

The ventricles and valves are surgically excised, and the device is sewn to the remaining atria (top half of the heart). The TAH replaces the function of the two ventricles and four valves by pumping blood to both the pulmonary and systemic circulation. The TAH provides circulatory support while waiting for a donor heart and may also restore kidney and liver function due to improved blood flow.

The TAH is connected to two lines that exit through the skin and connect to a large power generating console, which operates and monitors the device, while the patient is hospitalized. A portable power generating device (Freedom Driver System) is also available which allows the patient to leave the hospital.

### **Ventricular Assist Devices**

A ventricular assist device (VAD), also known as a mechanical circulatory support device, is an implantable mechanical pump that helps pump blood from the lower chambers of the heart (the ventricles) to the rest of the body. A VAD is used in individuals with weakened hearts or heart failure. A VAD can be implanted while waiting for a heart transplant or for the heart to become strong enough to effectively pump blood on its own. A VAD can also be implanted as long-term treatment if the individual has heart failure and is not a candidate for heart transplant.

Percutaneous VADs (pVADs), also referred to as percutaneous circulatory support devices, are proposed as an alternative to traditional VADs for short-term hemodynamic support in high-risk patients undergoing percutaneous coronary intervention (PCI), acute decompensated heart failure, and acute myocardial infarction (MI) with or without cardiogenic shock.

### **FDA Approval**

#### **Total Artificial Heart**

The SynCardia temporary Total Artificial Heart (TAH-t), formerly known as SynCardia temporary CardioWest™ Total Artificial Heart, approved by the FDA in October 2004 for in-hospital use as a bridge to heart transplantation in individuals with biventricular heart failure who have failed optimal medical therapy, are at imminent risk of death and are currently listed as a heart transplant candidate.

The SynCardia Freedom® Driver System, marketed as SynCardia temporary Total Artificial Heart with the Freedom® Driver System, was approved by the FDA in June 2014 for use as a bridge to transplantation in cardiac transplant candidates who have been implanted with the SynCardia TAH-t and are clinically stable.

AbioCor® Implantable Replacement Heart. This device was granted a humanitarian device exemption (HDE).

### **Ventricular Assist Devices**

FDA approved ventricular devices include:

- Thoratec(R) Ventricular Assist Device (VAD) System (PMA-P870072)
- Thoratec HeartMate II LVAS (PMA-P060040)
- Heartware® Ventricular Assist System (PMA-P100047)
- HeartMate 3™ Left Ventricular Assist System (LVAS) (PMA-P160054/S008)
- Levitronix Centrimag® Right Ventricular Assist System (RVAS). This device was granted a humanitarian device exemption (HDE).
- The Impella Recover® LP 2.5 Percutaneous Cardiac Support System (K063723 Abiomed, Danvers, MA.)
- TandemHeart® PTVA® System (CardiacAssist, Inc., Pittsburgh, PA)
- HeartAssist 5®, formerly called the DeBakey VAD® Child Left Ventricular Assist System (MicroMed Technology, Houston TX.). This device was granted a humanitarian device exemption (HDE)

- Berlin Heart EXCOR® Pediatric Ventricular Assist Device. This device was granted a humanitarian device exemption (HDE).
- Impella RP System. This device was granted a humanitarian device exemption (HDE).

## **Prior Authorization**

Prior authorization is not required. However, notification is required. Please refer to [medica.com](http://medica.com) for the notification form. Services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

## **Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

### **Total Artificial Heart CPT Codes:**

- 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)

### **Ventricular Assist Device CPT Codes:**

- 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
- 33990 - Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only 3991 - both arterial and venous access, with transseptal puncture
- 33991 - Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
- 33993 - Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion (On policy - not on set up sheet)
- 33995 - Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only (on set up sheet – not on policy)
- 33997 - Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion (on set up sheet – not on policy)
- 0451T - Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)
- 0452T - Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)
- 0453T - Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface

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- 0454T - Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode

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### HCPC Codes:

- L8698 - Miscellaneous component, supply or accessory for use with total artificial heart system
- Q0478 - Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
- Q0507 - Misc supply or accessory for use with an external VAD
- Q0508 - Misc supply or accessory for use with an implanted VAD
- Q0509 - Misc supply or accessory for use with and external VAD for which payment was not made under Medicare Part A

**Original Effective Date Coverage Policy *Mechanical Circulatory Support Device*:** 2/15/2021

Re-Review Date(s): 11/15/2023

**Original Effective Date Coverage Policy *Ventricular Assist Device*:** 7/1/2010

Re-Review Date 3/26/2013

**Original Effective Date UM Policy *Mechanical Circulatory Support Device*:** 6/1/2014

Re-Review Date(s) UM Policy:

- 2/1/2015
- 4/1/2016
- 2/1/2017
- 2/1/2018
- 2/1/2019
- 2/1/2020

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