

## Artificial Hearts and Ventricular Assist Devices

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|---------------------------------|---|
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| <b>Approved By:</b>             | Highmark Health Options – Market Leadership |
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| <b>Application:</b>             | TBD   |
| <b>Page Number(s):</b>          | 1-10  |

### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Ventricular assist devices (VADs) are devices which either replace all or part of a human heart or assist the heart in performing its pumping function. Artificial hearts may be used as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant. Percutaneous assist devices (pVADS), also known as circulatory assist devices, are small mechanical pumps typically inserted through a femoral artery with the proposed use as a short-term bridge to recovery.

Total artificial hearts (TAHs) replace the native ventricles and are attached to the pulmonary artery and aorta; the native ventricles are removed. TAHs are covered only if they have received approval from the U.S. FDA for that purpose, and the TAHs are used in accordance with the following U.S. FDA approved usages.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently serves Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan and Health Plan Plus members.

### POLICY POSITION

#### 1. VADs

VADs, that are approved by the United States Food and Drug Administration (U.S. FDA) for that purpose (e.g., HeartMate III LVAD, HeartWare HVAD), may be considered medically necessary when ANY of the following are met:

- Postcardiotomy ventricular dysfunction; or

- Treatment of right heart failure following insertion of an implantable left ventricular device; or
- Treatment of cardiogenic shock following cardiac transplantation.

VADs used as a bridge to transplant may be considered medically necessary when ALL the following are met:

- Candidate for cardiac transplantation; and
- Imminent risk of dying before donor heart procurement; and
- Dependence on, continued vasopressor support.

U.S. FDA approved VADs may be considered medically necessary as a bridge to heart transplantation in children when used in accordance with the FDA's Humanitarian Device Exception (HDE) requirements when ALL of the following are met:

- Body surface area (BSA) greater than or equal to 0.7 m<sup>2</sup> and less than 1.5 m<sup>2</sup>; and
- In NYHA Class IV end-stage (i.e., left ventricular) heart failure refractory to medical therapy; and
- Listed candidate for cardiac transplantation; and
- An age appropriate VAD will be used until a donor heart can be obtained.

Treatment is allowed with any U.S. FDA approved device for children based on ages listed below as follows:

- Child under age five (5): the Berlin Heart EXCOR<sup>®</sup> Pediatric Ventricular Assist Device; or
- Child between ages five (5) and 16: either 5 Pediatric Ventricular Assist Device or the Berlin Heart EXCOR<sup>®</sup> Pediatric Ventricular Assist Device.

U.S. FDA approved VADs for children may be considered medically necessary as a bridge to heart transplantation including, but not limited to, the following indications:

- Acute or chronic cardiac insufficiency due to various medical conditions such as an equivalent to recovery or transplantation for ANY of the following indications:
  - Myocarditis; or
  - Cardiomyopathy; or
  - NYHA class III or IV congenital heart failure that cannot be treated with conservative methods.

Pediatric VADs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature in children who meet ANY of the following criteria:

- Have a blood-clotting (primary coagulopathy) or platelet disorder such as hemophilia or Von Willebrand's disease; or
- Have anatomical anomalies that would prevent surgical connection of the outflow graft to the ascending aorta.

VADs used as destination therapy may be considered medically necessary when ALL the following are met:

- The device has received U.S. FDA approval for a destination therapy indication; and

- Individual has New York Heart Association (NYHA) Class III or IV end-stage ventricular heart failure and is not a candidate for heart transplant; and
- Individual has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for seven (7) days, or has been IV inotrope dependent for 14 days; and
- Has a left ventricular ejection fraction (LVEF) less than 25 percent; and
- Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min.

VADs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature for ANY of the following:

- Any medical condition that, if corrected, would improve heart function; or
- Any condition that could result in a poor surgical risk; or
- Stroke, impaired cognitive function, history of severe cerebral vascular disease; or
- Severe-end organ damage.

## 2. Percutaneous ventricular assist devices (pVAD)

U.S. FDA approved pVADs are intended for partial circulatory support. The Impella® circulatory support system devices or the TandemHeart® (cardiac assist device) may be considered medically necessary for short-term stabilization of individuals with ANY of the following indications:

- Cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP); or
- Cardiogenic shock, as an alternative to IABP; or
- High-risk individuals undergoing invasive cardiac/electrophysiological procedures who need circulatory support; or
- Ongoing acute myocardial infarction (MI) in individuals at risk for hemodynamic compromise from un-vascularized severe Coronary Artery Disease (CAD).

pVADs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

pVADs, including but not limited to the Impella devices and TandemHeart cardiac devices are contraindicated for ANY of the following:

- Mechanical aortic valve or heart constrictive device; or
- Aortic valve stenosis/calcification (graded as  $\geq +2$  (two) equivalent to an orifice area of 1.5 cm<sup>2</sup> or less); or
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as  $\geq +2$  (two)).

The use of non-U.S. FDA approved or cleared pVADs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

## 3. Total artificial hearts (TAHs)

U.S. FDA-approved devices TAHs (e.g., SynCardia Temporary Total Artificial Heart) may be considered medically necessary as a bridge to heart transplantation for individuals when ALL of the following are met:

- For individuals with biventricular failure who have no other reasonable medical or surgical treatment options; and
- Who are ineligible for other univentricular or biventricular support devices; and
- Currently listed as heart transplantation candidates; and
- Not expected to survive until a donor heart can be obtained.

TAHs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, noncovered, because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

The use of TAHs as destination therapy not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

The use of non-U.S. FDA approved or cleared implantable TAHs not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Conditions that may exclude individuals for heart transplant:

- Chronic irreversible hepatic, renal, or respiratory failure; or
- Systemic infection; or
- Coagulation disorders; or
- Inadequate psychosocial support.

## **NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATION OF HEART FAILURE**

| <b>Class</b> | <b>Description</b>   |
|--------------|--|
| Class I      | No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.                                    |
| Class II     | Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.           |
| Class III    | Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations. |
| Class IV     | Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.   |

## **PROFESSIONAL STATEMENTS AND SOCIETAL POSITIONS GUIDELINES**

### **American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation-2020**

The American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation published guidelines on selected topics in mechanical circulatory support, including recommendations on the use of pVADs (Table 10). The guideline authors noted, "Compared with IABP,

contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

**Table 10. 2020 guidelines on mechanical circulatory support**

| Recommendation  | COE | LOE |
|---|-----|-----|
| "Percutaneous LV to aorta pumps of appropriate size should be considered or cardiogenic shock from primary LV failure." | IIA | B   |

**American College of Cardiology Foundation et al-2017**

The American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA. Left ventricular assist device was one of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after guidelines-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then left ventricular assist device would be an additional treatment option.

The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged. The American College of Cardiology Foundation and AHA (2013) released guidelines for the management of heart failure that included recommendations related to the use of MCS, including both durable and nondurable MCS devices. The guidelines categorized pVADs and extracorporeal VADs as nondurable MCS devices. Table 11 provides class IIA guidelines on MCS devices.

**Table 11. 2017 Guidelines On Mechanical Circulatory Support**

| Recommendation   | COE | LOE |
|--|-----|-----|
| "MCS is beneficial in carefully selected patients with stage D HFrEF in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned."   | IIA | B   |
| "Nondurable MCS, including the use of percutaneous and extracorporeal ventricular assist devices (VADs), is reasonable as a 'bridge to recover' or 'bridge to decision' for carefully selected patients with HFrEF with acute, profound hemodynamic compromise." | IIA | B   |
| "Durable MCS is reasonable to prolong survival for carefully selected patients with stag D HFrEF."   | IIA | B   |

**NONCOVERED SERVICES**

Experimental/investigational (E/I) services are not covered regardless of place of service.

**ELIGIBLE PROCEDURE CODES**

| CPT codes | Description   |
|-----------|---|
| 33927     | Implantation of 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 | Removal 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 (e.g., drivelines alarms power surges) review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report. |
| L8698 | Miscellaneous component, supply or accessory for use with total artificial heart system.  |

**ELIGIBLE DIAGNOSIS CODES FOR PROCEDURE CODES 33927, 33928, 33929, 33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 33990, 33991, 33992, 33993, 33995, 33997, L8698**

| Code    |         |         |         |         |         |         |
|---------|---------|---------|---------|---------|---------|---------|
| I09.81  | I11.0   | I13.0   | I13.2   | I20.0   | I21.01  | I21.02  |
| I21.09  | I21.11  | I21.19  | I21.21  | I21.29  | I21.3   | I21.4   |
| I21.9   | I21.A1  | I21.A9  | I22.0   | I22.1   | I22.2   | I22.9   |
| I24.0   | I24.1   | I24.8   | I24.9   | I25.10  | I25.110 | I25.111 |
| I25.118 | I25.119 | I25.5   | I25.6   | I25.700 | I25.701 | I25.708 |
| I25.709 | I25.710 | I25.711 | I25.718 | I25.719 | I25.720 | I25.721 |
| I25.728 | I25.729 | I25.730 | I25.731 | I25.738 | I25.739 | I25.750 |
| I25.751 | I25.758 | I25.759 | I25.760 | I25761. | I25.768 | I25.769 |
| I25.790 | I25.791 | I25.798 | I25.799 | I25.810 | I25.811 | I25.812 |

|          |          |          |          |          |          |          |
|----------|----------|----------|----------|----------|----------|----------|
| I25.89   | I25.9    | I34.0    | I34.1    | I34.2    | I34.8    | I34.9    |
| I35.0    | I35.1    | I35.2    | I35.8    | I35.9    | I36.0    | I36.1    |
| I36.2    | I36.8    | I36.9    | I37.0    | I37.1    | I37.2    | I37.8    |
| I37.9    | I42.0    | I42.1    | I42.2    | I42.5    | I42.7    | I42.8    |
| I42.9    | I43      | I46.2    | I46.8    | I46.9    | I47.0    | I47.1    |
| I47.2    | I47.9    | I48.0    | I49.01   | I49.02   | I49.1    | I49.2    |
| I49.3    | I49.40   | I49.49   | I49.5    | I49.8    | I49.9    | I50.1    |
| I50.20   | I50.21   | I50.22   | I50.23   | I50.30   | I50.31   | I50.32   |
| I50.33   | I50.40   | I50.41   | I50.42   | I50.43   | I50.810  | I50.811  |
| I50.812  | I50.813  | I50.814  | I50.82   | I50.83   | I50.84   | I50.89   |
| I50.9    | I51.4    | I97.0    | I97.110  | I97.111  | I97.120  | I97.121  |
| I97.130  | I97.131  | I97.190  | I97.191  | I97.710  | I97.711  | I97.790  |
| I97.791  | M32.11   | Q20.0    | Q20.1    | Q20.2    | Q20.3    | Q20.4    |
| Q20.5    | Q20.6    | Q20.8    | Q20.9    | Q21.0    | Q21.1    | Q21.2    |
| Q21.3    | Q21.4    | Q21.8    | Q21.9    | Q22.0    | Q22.1    | Q22.2    |
| Q22.3    | Q22.4    | Q22.5    | Q22.6    | Q22.8    | Q22.9    | Q23.0    |
| Q23.1    | Q23.2    | Q23.3    | Q23.4    | Q23.8    | Q23.9    | Q24.0    |
| Q24.1    | Q24.2    | Q24.3    | Q24.4    | Q24.5    | Q24.6    | Q24.8    |
| Q24.9    | R00.1    | R572.0   | T82.817A | T82.827A | T82.837A | T82.847A |
| T82.857A | T82.867A | T82.897A | T82.9XXA | T86.20   | T86.21   | T86.22   |
| T86.23   | T86.290  | T86.298  | T86.30   | T86.31   | T86.32   | T86.33   |
| T86.39   | Z48.21   | Z48.280  | Z76.82   | Z94.1    | Z94.3    | Z95.811  |
| Z95.812  | Z95.818  |          |          |          |          |          |

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**POLICY UPDATE HISTORY**

| <Date> | <Event> |
|--------|---------|
|--------|---------|