Artificial Hearts and Ventricular Assist Devices

Policy ID:	HHO-DE-MP-1104
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	N/A
Annual Approval Date:	10/2022
Last Revision Date:	10/08/2021
Products:	Medicaid
Application:	TBD
Page Number(s):	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^2 and less than 1.5 m^2; 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® Pediatric Ventricular Assist Device; or
- Child between ages five (5) and 16: either 5 Pediatric Ventricular Assist Device or the Berlin Heart EXCOR® 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 ≥ +2 (two) equivalent to an orifice area of 1.5 cm^2 or less); or
   - Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +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

Class	Description
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					

References

Acharya D, Loyaga-Rendon RY, Pamboukian SV, et al. Ventricular assist device in acute myocardial infarction. J Am Coll Cardiol. 2016;67(16):1871-1880.

Acharya D. Ventricular assist device in acute myocardial infarction. J Am Coll Cardiol. 2016;67(16):1781-1880.

Agrawal S, Garg L, Shah M, et al. Thirty-day readmissions after left ventricular assist device implantation in the united states: Insights from the nationwide readmissions database. Circ Heart Fail. 2018;11(3):e004628.

Ait Ichou J, Larivee N, Eisenberg MJ, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Catheter Cardiovasc Interv. 2018;91(7):1250-1260.

Al-Sarie M, Rauf A, Kfoury AG, et al. Myocardial structural and functional response after long-term mechanical unloading with continuous flow left ventricular assist device: Axial versus centrifugal flow. JACC Heart Fail. 2016;4(7):570-576

Blume ED, Rosenthal DN, Rossano JW, et al. Outcomes of children implanted with ventricular assist devices in the United States: First analysis of the pediatric interagency registry for mechanical circulatory support (PediMACS). J Heart Lung Transplant. 2016;35(5):578-84.

Bulic A, Maeda K, Zhang Y, et al. Functional status of United States children supported with a left ventricular assist device at heart transplantation. J Heart Lung Transplant. 2017;36(8):890-6.

Chen S. Outpatient outcomes of pediatric patients with left ventricular assist devices. ASAIO J. 2016;163-168.

CMS Online Manual Pub.100-3, National Coverage Determination (NCD) for Artificial Hearts and Related Devices. Section 20.9.

Colombo PC, Mehra MR, Goldstein DJ, et al. Comprehensive analysis of stroke in the long-term cohort of the Momentum 3 study. Circ. 2019;139(2):155-168.

Conway J, Al-Aklabi M, Granoski D, et al. Supporting pediatric patients with short-term continuous-flow devices. J Heart Lung Transplant. 2016;35(5):603-9.

Cook JL, Colvin M, Francis GS, et al Recommendations for the use of mechanical circulatory support: Ambulatory and community patient care: A scientific statement from the American Heart Association. Circ. 2017;135(25):e1145-58.

Ergle K, Parto P, Krim SR. Percutaneous ventricular assist devices: A novel approach in the management of patients with acute cardiogenic shock. Ochsner J. 2016;16(3):243-9.

Food and Drug Administration. Summary of safety and probable benefit - H040006: AbioCor implantable replacement heart. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf. Accessed April 2020.

Grimm JC, Sciortino CM, Magruder JT, et al. Outcomes in patients bridged with univentricular and biventricular devices in the modern era of heart transplantation. Ann Thorac Surg. 2016;102(1):102-8.

Hayes, Inc. Hayes Health Technology Assessment. FDA Safety alert: Medtronic HVAD pump implant kits. Lansdale, PA. Hayes, Inc.; 03/20/2021.

Hayes, Inc. Health Technology Assessment. Total artificial heart, temporary or permanent, biventricular mechanical circulatory support device. Lansdale, Pa: Hayes, Inc; 06/2019.

InterQual® Level of Care Criteria 2019. Acute Care Adult. Change Healthcare, LLC.

Kirklin JK, Pagani FD, Goldstein DJ, et al. American association for thoracic surgery/international society for heart and lung transplantation guidelines on selected topics in mechanical circulatory support. J Heart Lung Transplant. 2020;39(3):187-219.

Mehra MR, Naka Y, Uriel N, et al. A fully magnetically levitated circulatory pump for advanced heart failure. N Engl J Med. 2017;376(5):440-450.

Mehra MR, Uriel N, Naka Y, et al. A fully magnetically levitated left ventricular assist device-final report. N Engl J Med. 2019;380(17):1618-1627.

Muthiah K. Longitudinal structural, functional, and cellular myocardial alterations with chronic centrifugal continuous-flow left ventricular assist device support. J Heart Transplant. 2017;36(7):722-731.

Nelson McMillan K, Hibino N, Brown EE, et al. HeartWare ventricular assist device implantation for pediatric heart failure—A single center approach. Artif Organs. 2019;43(1):21-9.

Ouweneel DM, de Brabander J, Karami M, et al. Real-life use of left ventricular circulatory support with Impella in cardiogenic shock after acute myocardial infarction: 12 years AMC experience. Eur Heart J Acute Cardiovasc Care. 2019;8(4):338-349.

Ouweneel DM, Eriksen E, Sjauw KD, et al. Percutaneous mechanical circulatory support versus intraaortic balloon pump in cardiogenic shock after acute myocardial infarction. J Am Coll Cardiol. 2017;69(3):278-287.

PROTECT II: A prospective, multi-center, randomized controlled trial of the Impella Recover LP System versus intra-aortic balloon pump (IABP) in patients undergoing non emergent high risk PCI. Clinical trials.gov.

Rogers JG, Pagani FD, Tatooles AJ, et al. Intrapericardial left ventricular assist device for advanced heart failure. N Engl J Med. 2017;376(5):451-460.

Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. World J Cardiol. 2016;8(1):98-111.

Schafer A, Werner N, Burkhoff D, et al. Influence of timing and predicted risk on mortality in impellatreated infarct-related cardiogenic shock patients. Front Cardiovasc Med. 2020;7:74.

Schrage B, Ibrahim K, Loehn T, et al. Impella support for acute myocardial infarction complicated by cardiogenic shock. Circ. 2019;139(10):1249-1258.

Sieweke JT, Berliner D, Tongers J, et al. Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated left ventricular failure. Eur Heart J Acute Cardiovasc Care. 2020;9(2):138-148.

Starling RC, Estep JD, Horstmanshof DA, et al. Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: The roadmap study 2-year results. JACC Heart Fail. 2017;5(7):518-527.

Stehlik J, Estep JD, Selzman CH. Patient-reported health-related quality of life is a predictor of outcomes in ambulatory heart failure patients treated with left ventricular assist device compared with medical management: Results from the ROADMAP study (Risk assessment and comparative effectiveness of left ventricular assist device and medical management). Circ Heart Fail. 2017;10(6):e003910.

Villa CR, Moore RA, Lorts A. The total artificial heart in pediatrics: Outcomes in an evolving field. Ann Cardiothorac Surg. 2020;9(2):104-109.

Wehman B, Stafford KA, Bittle GJ, et al. Modern outcomes of mechanical circulatory support as a bridge to pediatric heart transplantation. Ann Thorac Surg. 2016;101(6):2321-2327.

Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of cardiology/American heart association task force on clinical practice guidelines and the heart failure Society of America. Circ. 2017;136(6):e137-e161.

POLICY UPDATE HISTORY

<Date>	<Event>