MEDICAL POLICY

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

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I. POLICY

Bridge to Transplantation
Implantable ventricular assist devices (VADs) with Food and Drug Administration (FDA) approval or clearance may be considered **medically necessary** as a bridge to heart transplantation for patients who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Implantable VADs with FDA approval or clearance, including humanitarian device exemptions, may be considered **medically necessary** as a bridge to heart transplantation in children 16 years old or younger who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Total artificial hearts (TAHs) with FDA-approved devices may be considered **medically necessary** as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates, and not expected to survive until a donor heart can be obtained.

Destination Therapy
Implantable VADs with FDA approval or clearance may be considered **medically necessary** as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following "REMATCH Study" criteria:

- New York Heart Association (NYHA) class IV heart failure for ≥60 days, OR

- Patients in NYHA class III/IV for 28 days, received ≥14 days' support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:

- Age >65 years; OR
- Insulin-dependent diabetes mellitus with end-organ damage; OR
- Chronic renal failure (serum creatinine >2.5 mg/dL for >90 days; OR
- Presence of other clinically significant condition.

Postcardiotomy Setting/Bridge to Recovery

Implantable VADs with FDA approval or clearance may be considered **medically necessary** in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

Other Indications

Other applications of implantable VADs or TAHs are considered **investigational**, including, but not limited to, the use of total artificial hearts as destination therapy.

The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered **investigational.**

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

Policy Guidelines

Only two ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey VAD® Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the humanitarian device exemption (HDE) process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant, (i.e., as a bridge to transplant) while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

In general, candidates for bridge to transplant implantable VADs are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of less than 2.0 L/min/m while receiving maximal medical support. Patients with VADs are classified by the United Network for Organ Sharing as status I (ie, persons who are most ill and are considered the highest priority for transplant).

The median duration for time on the device is between 20 and 120 days.

Contraindications for bridge to transplant VADs and total artificial hearts include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders, and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or total artificial heart, implantation is also contraindicated in patients with uncorrected valvular disease.

In addition, individuals must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest™ temporary Total Artificial Heart, this excludes individuals with body surface areas less than 1.7 m^2 or who have a distance between the sternum and 10^{th} anterior rib of less than 10 cm as measured by CT [computed tomography] scan.

Cross-reference:
MP-9.007 Heart Transplant
MP-9.014 Heart/Lung Transplant

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - For implantation of an artificial heart as a bridge to transplant or destination therapy, refer to the FEP Benefit Plan Brochure found at: www.fepblue.org. Regarding ventricular assist devices, refer to FEP Medical Policy Manual MP-7.03.11, Total Artificial Hearts and Implantable Ventricular Assist Devices. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

HEART FAILURE

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1, 3, and 5 years of about 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

Treatment

Ventricular Assist Devices

Implantable ventricular assist devices (VADs) are attached to the native heart, which may have enough residual capacity to withstand a device failure in the short term. In reversible heart failure conditions, the native heart may regain some function, and weaning and explanting of the mechanical support system after months of use has been described. VADs can be classified as internal or external, electrically or pneumatically powered, and pulsatile or continuous-flow. Initial devices were pulsatile, mimicking the action of a beating heart. More recent devices may use a pump, which provides continuous flow. Continuous devices may move blood in a rotary or axial flow.

At least 1 VAD system developed is miniaturized and generates an artificial pulse, the HeartMate 3 Left Ventricular Assist System.

Surgically implanted VADs represent a method of providing mechanical circulatory support for patients not expected to survive until a donor heart becomes available for transplant or for whom transplantation is contraindicated or unavailable. VADs are most commonly used to support the left ventricle, but right ventricular and biventricular devices may be used. The device is larger than most native hearts, and therefore the size of the patient is an important consideration; the pump may be implanted in the thorax or abdomen or remain external to the body. Inflow to the device is attached to the apex of the failed ventricle, while outflow is attached to the corresponding great artery (aorta for the left ventricle, a pulmonary artery for the right ventricle). A small portion of the ventricular wall is removed for insertion of the outflow tube; extensive cardiotomy affecting the ventricular wall may preclude VAD use.

Total Artificial Hearts

Initial research into mechanical assistance for the heart focused on the total artificial heart (TAH), a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in 2 patients but is currently experimental.

Regulatory Status

A number of mechanical circulatory support devices have received approval or clearance for marketing by FDA. These devices are summarized in Table 1, and described further in following sections.

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

Table 1. Available Mechanical Circulatory Support Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
Thoratec IVAD	Thoratec	Aug 2004	PMA Supp	P870072	Bridge to transplant and postcardiotomy
DeBakey VAD® Child	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in children 5-16 y
HeartMate II	Thoratec	Apr 2008	PMA	P060040	Bridge to transplant and destination
CentriMag	Levitronix (now Thoratec)	Oct 2008	HDE	H070004	Postcardiotomy
Berlin Heart EXCOR® Pediatric VAD	Berlin	Dec 2011	HDE	H100004	Bridge to transplant
HeartWare® Ventricular Assist System	HeartWare	Dec 2012	PMA	P100047	Bridge to transplant
HeartMate 3 Left Ventricular Assist System	Thoratec	Aug 2017 Oct 2018	PMA PMA	P160054 P160054/S008	Bridge to transplant Destination

FDA: U.S. Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval.

Ventricular Assist Devices

In 1995, the Thoratec® Ventricular Assist Device System (Thoratec Corp.) was approved by FDA through the premarket approval process as a bridge to transplantation in patients suffering from end-stage heart failure. The patient should meet all of the following criteria:

- candidate for cardiac transplantation,
- imminent risk of dying before donor heart procurement, and
- dependence on, or incomplete response to, continuous vasopressor support.

In 1998, supplemental approval for this device was given for the indication of postcardiotomy patients unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital when accompanied by a trained caregiver. In 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In 2004, supplemental approval was given to a modified device to be marketed as the Thoratec® Implantable VAD for the same indications. In 2008, supplemental approval was given to rescind Paracorporeal VAD use.

In August 2016, HeartWare® recalled its VAD Pumps due to a design flaw that was deemed by FDA as potentially causing serious injuries or death (class I recall). The devices affected were manufactured and distributed from March 2006 and May 2018. FDA product codes 204 and 017.

A class I recall was issued for the HeartMate 3™ in April 2018 affecting all manufacturing dates. FDA product code: DSQ.

Total Artificial Heart

In 2004, the temporary CardioWest™ Total Artificial Heart (SynCardia Systems) was approved by FDA through the premarket approval process for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. This device is also intended for use inside the hospital. In 2010, FDA approved a name change to SynCardia Temporary Total Artificial Heart. FDA product code: LOZ.

In 2006, the AbioCor® Implantable Replacement Heart System (Abiomed) was approved by FDA through the humanitarian device exemption (H040006) process in severe biventricular end-stage heart disease patients who are not cardiac transplant candidates and who:

- are younger than 75 years of age;
- require multiple inotropic support;
- are not treatable by left VAD destination therapy; and
- are not weanable from biventricular support if on such support.

In addition to meeting other criteria, patients who are candidates for the AbioCor® TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men.

IV. RATIONALE

TOP

SUMMARY OF EVIDENCE

Ventricular Assist Device

For individuals who have end-stage heart failure who receive a VAD as a bridge to transplant, the evidence includes single-arm trials and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. There is a substantial body of evidence from clinical trials and observational studies supporting implantable VADs as a bridge to transplant in patients with end-stage heart failure, possibly reducing mortality as well as improving quality of life. These studies have reported that substantial numbers of patients have survived to transplant in situations in which survival would not be otherwise expected. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes a trial and multiple single-arm studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. A well-designed trial, with 2 years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for heart transplant. Despite an increase in adverse events, both mortality and quality of life appear to be improved for these

patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Total Artificial Heart

For individuals who have end-stage heart failure who receive a TAH as a bridge to transplant, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

TOP

CARDIOTOMY refers to an incision of the heart**.**

DESTINATION THERAPY refers the intention of permanent use.

NEW YORK HEART ASSOCIATION CLASS III refers to patients with cardiac disease which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV refers to patients with cardiac disease which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are

different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Non FDA approved services are considered investigational; therefore, not covered (e.g. iVAS):

CPT Codes®								
0451T	0452T	0453T	0454T	0455T	0456T	0457T	0458T	0459T
0460T	0461T	0462T	0463T					

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Covered when medically necessary:

CPT Codes®								
33927	33928	33929	33975	33976	33977	33978	33979	33980

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HCPCS Codes	Description
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/ electric pneumatic ventricular assist device, vehicle type

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

HCPCS Codes	Description
Q0479	Power module for use with electric or 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 back 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 for use with electric or electric/pneumatic ventricular assist device, replacement only

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

HCPCS Codes	Description
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

ICD-10-CM Diagnosis Codes	Description
I09.81	Rheumatic heart failure (congestive)
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure with stage 5 chronic kidney disease, or end stage renal disease
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart
I50.41	Acute combined systolic (congestive)
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

ICD-10-CM Diagnosis Codes	Description
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Heart failure, unspecified
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I97.0	Postcardiotomy syndrome

IX. REFERENCES

TOP

1. *Organ Procurement and Transplantation Network. Heart Kaplan-Meier Patient Survival Rates For Transplants Performed : 2008 - 2015. 2018; https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14561. Accessed September 30, 2019.*
2. *Netuka I, Sood P, Pya Y, et al. Fully magnetically levitated left ventricular assist system for treating advanced HF: a multicenter study. J Am Coll Cardiol. Dec 15 2015;66(23):2579-2589. PMID 26670056*
3. *Carpentier A, Latremouille C, Cholley B, et al. First clinical use of a bioprosthetic total artificial heart: report of two cases. Lancet. Oct 17 2015;386(10003):1556-1563. PMID 26231456*
4. *Mehra MR, Naka Y, Uriel N, et al. A fully magnetically levitated circulatory pump for advanced heart failure. N Engl J Med. Feb 02 2017;376(5):440-450. PMID 27959709*
5. *Rogers JG, Pagani FD, Tatooles AJ, et al. Intrapericardial left ventricular assist device for advanced heart failure. N Engl J Med. Feb 02 2017;376(5):451-460. PMID 28146651*
6. *Mehra, M, Uriel, N, Naka, Y, et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. N. Engl. J. Med., 2019 Mar 19;380(17). PMID 30883052.*
7. *Colombo, P, Mehra, M, Goldstein, D, et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. Circulation, 2018 Dec 28;139(2). PMID 30586698.*
8. *Cowger, J, Naka, Y, Aaronson, K et al. Quality of life and functional capacity outcomes in the MOMENTUM 3 trial at 6 months: A call for new metrics for left ventricular assist device patients. J. Heart Lung Transplant., 2017 Nov 21;37(1). PMID 29153637.*

9. *Pruijsten RV, Lok SI, Kirkels HH, et al. Functional and haemodynamic recovery after implantation of continuous- flow left ventricular assist devices in comparison with pulsatile left ventricular assist devices in patients with end- stage heart failure. Eur J Heart Fail. Mar 2012;14(3):319-325. PMID 22294758.*
10. *Lim KM, Constantino J, Gurev V, et al. Comparison of the effects of continuous and pulsatile left ventricular- assist devices on ventricular unloading using a cardiac electromechanics model. J Physiol Sci. Jan 2012;62(1):11-19. PMID 22076841.*
11. *Kato TS, Chokshi A, Singh P, et al. Effects of continuous-flow versus pulsatile-flow left ventricular assist devices on myocardial unloading and remodeling. Circ Heart Fail. Sep 2011;4(5):546-553. PMID 21765125.*
12. *Ventura PA, Alharethi R, Budge D, et al. Differential impact on post-transplant outcomes between pulsatile- and continuous-flow left ventricular assist devices. Clin Transplant. Jul-Aug 2011;25(4):E390-395. PMID 21401721.*
13. *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. Jul 2016;4(7):570-576. PMID 27179831.*
14. *Acharya D, Loyaga-Rendon RY, Pamboukian SV, et al. Ventricular assist device in acute myocardial infarction. J Am Coll Cardiol. Apr 26 2016;67(16):1871-1880. PMID 27102502.*
15. *Maybaum S, Mancini D, Xydas S, et al. Cardiac improvement during mechanical circulatory support: a prospective multicenter study of the LVAD Working Group. Circulation. May 15 2007;115(19):2497-2505. PMID 17485581.*
16. *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. PMID 29519902.*
17. *Takayama H, Soni L, Kalesan B, et al. Bridge-to-decision therapy with a continuous-flow external ventricular assist device in refractory cardiogenic shock of various causes. Circ Heart Fail. Sep 2014;7(5):799-806. PMID 25027874.*
18. *TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11;Tab 26.*
19. *Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. N Engl J Med. Nov 19 1998;339(21):1522-1533. PMID 9819452.*
20. *Slaughter MS, Pagani FD, McGee EC, et al. HeartWare ventricular assist system for bridge to transplant: combined results of the bridge to transplant and continued access protocol trial. J Heart Lung Transplant. Jul 2013;32(7):675-683. PMID 23796152.*
21. *Strueber M, O'Driscoll G, Jansz P, et al. Multicenter evaluation of an intrapericardial left ventricular assist system. J Am Coll Cardiol. Mar 22 2011;57(12):1375-1382. PMID 21414534.*

22. *Frazier OH, Gemmato C, Myers TJ, et al. Initial clinical experience with the HeartMate II axial-flow left ventricular assist device. Tex Heart Inst J. Oct 2007;34(3):275-281. PMID 17948075.*
23. *John R, Kamdar F, Liao K, et al. Improved survival and decreasing incidence of adverse events with the HeartMate II left ventricular assist device as bridge-to-transplant therapy. Ann Thorac Surg. Oct 2008;86(4):1227-1234; discussion 1234-1225. PMID 18805167.*
24. *Miller LW, Pagani FD, Russell SD, et al. Use of a continuous-flow device in patients awaiting heart transplantation. N Engl J Med. Aug 30 2007;357(9):885-896. PMID 17761592.*
25. *Patel ND, Weiss ES, Schaffer J, et al. Right heart dysfunction after left ventricular assist device implantation: a comparison of the pulsatile HeartMate I and axial-flow HeartMate II devices. Ann Thorac Surg. Sep 2008;86(3):832-840; discussion 832-840. PMID 18721570.*
26. *Struber M, Sander K, Lahpor J, et al. HeartMate II left ventricular assist device; early European experience. Eur J Cardiothorac Surg. Aug 2008;34(2):289-294. PMID 18571932.*
27. *Kirklin JK, Naftel DC, Stevenson LW, et al. INTERMACS database for durable devices for circulatory support: first annual report. J Heart Lung Transplant. Oct 2008;27(10):1065-1072. PMID 18926395.*
28. *Aissaoui N, Morshuis M, Maoulida H, et al. Management of end-stage heart failure patients with or without ventricular assist device: an observational comparison of clinical and economic outcomes. Eur J Cardiothorac Surg. 2018 53(1). PMID 28950304.*
29. *Schmitto, J, Pya, Y, Zimpfer, D, et al. Long-term evaluation of a fully magnetically levitated circulatory support device for advanced heart failure-two-year results from the HeartMate 3 CE Mark Study. Eur. J. Heart Fail., 2018 Jul 28;21(1). PMID 30052304.*
30. *Gustafsson, F, Shaw, S, Lavee, J, et al. Six-month outcomes after treatment of advanced heart failure with a full magnetically levitated continuous flow left ventricular assist device: report from the ELEVATE registry. Eur. Heart J., 2018 Aug 31;39(37). PMID 30165521.*
31. *Dickstein K, Cohen-Solal A, Filippatos G, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM). Eur Heart J. Oct 2008;29(19):2388-2442. PMID 18799522.*

32. *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. Aug 2017;36(8):890-896. PMID 28363739.*
33. *Wehman B, Stafford KA, Bittle GJ, et al. Modern outcomes of mechanical circulatory support as a bridge to pediatric heart transplantation. Ann Thorac Surg. Jun 2016;101(6):2321-2327. PMID 26912304.*
34. *Fraser CD, Jr., Jaquiss RD, Rosenthal DN, et al. Prospective trial of a pediatric ventricular assist device. N Engl J Med. Aug 09 2012;367(6):532-541. PMID 22873533.*
35. *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. May 2016;35(5):578-584. PMID 27009673.*
36. *Almond CS, Morales DL, Blackstone EH, et al. Berlin Heart EXCOR pediatric ventricular assist device for bridge to heart transplantation in US children. Circulation. Apr 23 2013;127(16):1702-1711. PMID 23538380.*
37. *Jordan LC, Ichord RN, Reinhartz O, et al. Neurological complications and outcomes in the Berlin Heart EXCOR(R) pediatric investigational device exemption trial. J Am Heart Assoc. Jan 2015;4(1):e001429. PMID 25613996.*
38. *Chen S, Lin A, Liu E, et al. Outpatient outcomes of pediatric patients with left ventricular assist devices. ASAIO J. Mar-Apr 2016;62(2):163-168. PMID 26720740.*
39. *Conway J, Al-Aklabi M, Granoski D, et al. Supporting pediatric patients with short-term continuous-flow devices. J Heart Lung Transplant. May 2016;35(5):603-609. PMID 27009672.*
40. *Aaronson KD, Eppinger MJ, Dyke DB, et al. Left ventricular assist device therapy improves utilization of donor hearts. J Am Coll Cardiol. Apr 17 2002;39(8):1247-1254. PMID 11955839.*
41. *Frazier OH, Rose EA, McCarthy P, et al. Improved mortality and rehabilitation of transplant candidates treated with a long-term implantable left ventricular assist system. Ann Surg. Sep 1995;222(3):327-336; discussion 336- 328. PMID 7677462.*
42. *Bank AJ, Mir SH, Nguyen DQ, et al. Effects of left ventricular assist devices on outcomes in patients undergoing heart transplantation. Ann Thorac Surg. May 2000;69(5):1369-1374; discussion 1375. PMID 10881807.*
43. *Shuhaiber JH, Hur K, Gibbons R. The influence of preoperative use of ventricular assist devices on survival after heart transplantation: propensity score matched analysis. BMJ. Feb 10 2010;340:c392. PMID 20147346.*
44. *Alba AC, McDonald M, Rao V, et al. The effect of ventricular assist devices on long-term post-transplant outcomes: a systematic review of observational studies. Eur J Heart Fail. Jul 2011;13(7):785-795. PMID 21551162.*

45. *Deo SV, Sung K, Daly RC, et al. Cardiac transplantation after bridged therapy with continuous flow left ventricular assist devices. Heart Lung Circ. Mar 2014;23(3):224-228. PMID 23954004.*
46. *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. Jul 2016;102(1):102-108. PMID 27068177.*
47. *Davies RR, Russo MJ, Hong KN, et al. The use of mechanical circulatory support as a bridge to transplantation in pediatric patients: an analysis of the United Network for Organ Sharing database. J Thorac Cardiovasc Surg. Feb 2008;135(2):421-427, 427 e421. PMID 18242279.*
48. *TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.*
49. *Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term mechanical left ventricular assistance for end-stage heart failure. N Engl J Med. Nov 15 2001;345(20):1435-1443. PMID 11794191.*
50. *Park SJ, Tector A, Piccioni W, et al. Left ventricular assist devices as destination therapy: a new look at survival. J Thorac Cardiovasc Surg. Jan 2005;129(1):9-17. PMID 15632819.*
51. *Long JW, Kfoury AG, Slaughter MS, et al. Long-term destination therapy with the HeartMate XVE left ventricular assist device: improved outcomes since the REMATCH study. Congest Heart Fail. May-Jun 2005;11(3):133-138. PMID 15947534.*
52. *Estep JD, Starling RC, Horstmanshof DA, et al. Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: results from the ROADMAP Study. J Am Coll Cardiol. Oct 20 2015;66(16):1747-1761. PMID 26483097.*
53. *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. Jul 2017;5(7):518-527. PMID 28396040.*
54. *Jorde UP, Kushwaha SS, Tatooles AJ, et al. Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS registry (Interagency Registry for Mechanically Assisted Circulatory Support). J Am Coll Cardiol. May 6 2014;63(17):1751-1757. PMID 24613333.*
55. *Rogers JG, Butler J, Lansman SL, et al. Chronic mechanical circulatory support for inotrope-dependent heart failure patients who are not transplant candidates: results of the INTrEPID Trial. J Am Coll Cardiol. Aug 21 2007;50(8):741-747. PMID 17707178.*
56. *Copeland JG, Smith RG, Arabia FA, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med. Aug 26 2004;351(9):859-867. PMID 15329423.*

57. *Copeland JG, Copeland H, Gustafson M, et al. Experience with more than 100 total artificial heart implants. J Thorac Cardiovasc Surg. Mar 2012;143(3):727-734. PMID 22245242.*
58. *Food and Drug Administration. Summay of Safety and Probable Benefit - H040006: AbioCor Implantable Replacement Heart. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf. Accessed September 30, 2019.*
59. *Dowling RD, Gray LA, Jr., Etoch SW, et al. Initial experience with the AbioCor implantable replacement heart system. J Thorac Cardiovasc Surg. Jan 2004;127(1):131-141. PMID 14752423.*
60. *Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. Nov-Dec 2014;60(6):626-634. PMID 25158888.*
61. *Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. World J Cardiol. Jan 26 2016;8(1):98-111. PMID 26839661.*
62. *Burkhoff D, Cohen H, Brunckhorst C, et al. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. Am Heart J. Sep 2006;152(3):469 e461-468. PMID 16923414.*
63. *Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol. Nov 4 2008;52(19):1584-1588. PMID 19007597.*
64. *Ouweneel DM, Eriksen E, Sjauw KD, et al. Percutaneous mechanical circulatory support versus intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. J Am Coll Cardiol. Jan 24 2017;69(3):278- 287. PMID 27810347.*
65. *Thiele H, Sick P, Boudriot E, et al. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. Eur Heart J. Jul 2005;26(13):1276-1283. PMID 15734771.*
66. *Schrage, B, Ibrahim, K, Loehn, T, et al. Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock. Circulation, 2018 Dec 28;139(10). PMID 30586755.*
67. *Griffith BP, Anderson MB, Samuels LE, et al. The RECOVER I: a multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. J Thorac Cardiovasc Surg. Feb 2013;145(2):548-554. PMID 22405676.*
68. *Lemaire A, Anderson MB, Lee LY, et al. The Impella device for acute mechanical circulatory support in patients in cardiogenic shock. Ann Thorac Surg. Jan 2014;97(1):133-138. PMID 24090575.*

69. *Lauten A, Engstrom AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail. Jan 2013;6(1):23-30. PMID 23212552.*
70. *Ouweneel, D, 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, 2018 Nov 8;8(4). PMID 30403366.*
71. *Ait Ichou, J, Larivée, N, Eisenberg, M, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Catheter Cardiovasc Interv, 2017 Sep 25;91(7). PMID 28941078.*
72. *O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. Oct 2 2012;126(14):1717-1727. PMID 22935569.*
73. *Briasoulis A, Telila T, Palla M, et al. Meta-analysis of usefulness of percutaneous left ventricular assist devices for high-risk percutaneous coronary interventions. Am J Cardiol. Aug 1 2016;118(3):369-375. PMID 27265673.*
74. *Reddy YM, Chinitz L, Mansour M, et al. Percutaneous left ventricular assist devices in ventricular tachycardia ablation: multicenter experience. Circ Arrhythm Electrophysiol. Apr 2014;7(2):244-250. PMID 24532564.*
75. *Aryana A, Gearoid O'Neill P, Gregory D, et al. Procedural and clinical outcomes after catheter ablation of unstable ventricular tachycardia supported by a percutaneous left ventricular assist device. Heart Rhythm. Jul 2014;11(7):1122-1130. PMID 24732372.*
76. *Kar B, Gregoric ID, Basra SS, et al. The percutaneous ventricular assist device in severe refractory cardiogenic shock. J Am Coll Cardiol. Feb 8 2011;57(6):688-696. PMID 20950980.*
77. *Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care: endorsed by the American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. J Am Coll Cardiol. May 19 2015;65(19):e7-e26. PMID 25861963.*
78. *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. Circulation. Apr 28 2017 136(6):e137-e161. PMID 28455343.*
79. *Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American*

Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Oct 15 2013;62(16):e147-239. PMID 23747642.

80. *Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. Circulation. Nov 27 2012;126(22):2648-2667. PMID 23109468.*
81. *Heart Failure Society of America, Lindenfeld J, Albert NM, et al. HFSA 2010 Comprehensive Heart Failure Practice Guideline. J Card Fail. Jun 2010;16(6):e1-194. PMID 20610207.*
82. *Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). 2013; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=ventricular+assist+devices&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed September 30, 2019.*
83. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.03.11, Total Artificial Hearts and Implantable Ventricular Assist Devices. September 2019.*

X. POLICY HISTORY

TOP

MP 1.026	**CAC 2/25/03**
	CAC 4/27/04
	CAC 10/26/04
	CAC 10/25/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus review
	CAC 4/26/11 Adopted BCBSA, No change to policy statements. Changed title. Additional criteria was listed for coverage of artificial hearts including no other treatment options, ineligible for ventricular support devices, currently listed as heart transplant candidates and not expected to survive until a donor heart is available. For ventricular assist devices additional criteria includes patients who are transplant candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for transplant.

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

	Added coverage criteria for coverage of VADs for children age 5-16. Deleted criteria for peak O2 consumption. Medicare variation updated.
	CAC 6/26/12 Investigational statement added for percutaneous ventricular assist devices.
	11/1/12 Due to provider feedback, administrative changes made regarding pVADs. Deleted statement "Percutaneous ventricular assist devices (pVADs) are considered **investigational** for all indications". Changed FEP variation to reference FEP Medical Policy Manual MP-7.03.11 Implantable Ventricular Assist Devices.
	7/29/13 Admin coding review complete
	CAC 9/24/13 Minor review. Policy statement on children amended; age range changed from 5-16 to 0-16, reflecting the approval of the BERLIN heart EXCOR device for pediatric patients aged 0-16. Added Rationale section. Updated references. Added policy guidelines section.
	CAC 9/30/14 Consensus. No change to policy statements. Rationale and reference sections updated.
	Administrative posting 1/1/15. FEP variation revised to refer to the FEP contract for implantation of an artificial heart as a bridge to transplant or destination therapy.
	Administrative posting 6/9/15. Table 1 revised to state the HeartWare device received FDA clearance via the PMA process, not HDE.
	CAC 9/29/15 Consensus review. No changes to the policy statements. Reference and rationale update. Coding reviewed and unranged.
	CAC 9/27/2016 Consensus review. No changes to the policy statements. Description/Background, Rationale and Reference sections updated (including removal of pVAD information). Coding reviewed; added new codes effective 1/1/17. New codes 0451T-0463T added; effective 1/1/17. Variation reformatting completed.
	Administrative Update 2/1/17: Clarified that new codes G0451T – G0463T, effective 1/1/17, are investigational since iVAS in not FDA approved.
	Administrative Update 10/1/17: Added new ICD 10 updates effective from 10/1/17.
	CAC 11/28/17 Consensus review. Policy statements were reordered but wording of the statements unchanged. Background, rationale and references updated**.** Coding reviewed. New codes 33927-33929 and Q0477 added plus end dated codes 0051T-0053T removed; effective 1/1/18.
	11/13/18 Consensus review. References updated. Rationale condensed.
	1/4/19 Admin Update: Added new code L8698 effective 1/1/19

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

	9/30/19 Consensus review. No changes to the policy statements. References updated.

Top