MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**RETIRED 3/1/2026**

I. POLICY

Destination Therapy

Implantable Ventricular Assist Devices (VADs) with U.S. Food and Drug Administration (FDA) approval or clearance may be considered **medically necessary** as destination therapy for adult individuals with end stage heart failure who meet the following criteria:

- New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV; **AND**
- Left ventricular ejection fraction ≤ 25%; **AND**
- Inotrope-dependent; OR cardiac index <2.2 liters/min/m2, while not on inotropes and also meeting one of the following:
  - On optimal medical management, based on current heart failure practice guidelines for at least 45 of the last 60 days and are failing to respond **OR**
  - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.

Bridge to Transplantation

Implantable VADs with FDA approval or clearance may be considered **medically necessary** as a bridge to heart transplantation for individuals who are:

- Currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, **OR**
- 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**

- 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 individuals with biventricular failure who:

- Have no other reasonable medical or surgical treatment options, are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates, **OR**
- Have no other reasonable medical or surgical treatment options, are ineligible for other univentricular or biventricular support devices, are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

Postcardiotomy Setting/Bridge to Recovery

Implantable VADs with FDA approval or clearance may be considered **medically necessary** in the postcardiotomy setting in individuals 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 TAHs 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 general conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

Policy Guidelines

The intent of treatment may evolve over the course of treatment; for example, there is not necessarily a strict delineation between bridge to transplant and destination therapy.

Some 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. The HeartMate3™ received approval for expanded approval for pediatric patients with advanced refractory left ventricular heart failure in 2020.

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. Individuals with VADs are classified by the United Network for Organ Sharing as status I (i.e., 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 individuals 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 individuals with uncorrected valvular disease. See evidence review 9.007 (Heart Transplant) for further discussion of heart transplant candidacy.

The Centers for Medicare and Medicaid Services requires that "Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least 1 physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least 1 cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Cross-Reference:

MP 9.007 Heart Transplant
MP 9.014 Heart/Lung Transplant

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

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 - Refer to FEP Medical Policy Manual. 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

A ventricular assist device (VAD) is mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy. The VAD has also been used as a bridge to recovery in individuals with reversible conditions affecting cardiac output.

Heart Failure

According to a 2024 report from the American Heart Association and based on data collected from 2017 to 2020, roughly 6.7 million Americans ages 20 years or older had heart failure during that time frame. Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years). Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socio-economic status.

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 had a reported survival rate of nearly 92% or transplants performed in 2022.. The number of candidates for transplants exceeds the supply of donor organs, thus the interest in the development of mechanical devices.

Devices and Regulatory Status

A number of implantable VADs and artificial heart systems have been U.S. Food and Drug Administration (FDA) approved through a Humanitarian Device Exemption, 510(k), or premarket approval regulatory pathway. This section discusses currently marketed devices.

FDA maintains a list of recent device recalls at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls.

Ventricular Assist Devices

Implantable 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.

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.

The intent of treatment may evolve over the course of treatment; for example, there is not necessarily a strict delineation between bridge to transplant and destination therapy, and transplant eligibility can change.

Table 1 lists the VADs currently available in the US. The HeartWare VAD System was discontinued in June 2021 due to evidence from observational studies demonstrating a higher frequency of neurological adverse events and mortality with the system compared to other commercially available LVADs. The HeartMate II and HeartMate 3 left VAD systems were recalled in April 2024 due to extrinsic outflow graft obstruction that can obstruct the device making it less effective. The recall was a corrective recall, and the devices remain on the market.

Table 1. Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication

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	Thoratec	Dec 2019	PMA	P170038	Postcardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	June 2017	PMA	P160035	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.

Total Artificial Hearts

The total artificial heart (TAH) is a biventricular device that completely replaces the function of the diseased heart. An internal battery requires 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.

Currently the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 2). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006 but is no longer being marketed or in development.

Table 2. Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	PMA No.	Indication
Syncardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and	SynCardia Systems	2004	510(k)	P8030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from

Jarvik Total Artificial Heart)					biventricular failure.

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 a randomized controlled trial (RCT), single-arm trials, and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life (QOL), 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 QOL. 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 an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes RCTs 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 a heart transplant. Despite an increase in adverse events, both mortality and QOL appear to be improved for these patients. A more recent trial comparing VADs has broader inclusion criteria and supports that criteria move away from use of transplant ineligibility, as treatment may evolve over the course of treatment. The evidence is sufficient to determine that the technology results in an 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 an 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 that the technology results in an improvement in the net health outcome.

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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies 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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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.

MEDICAL POLICY

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

Covered when medically necessary:

Procedure Codes								
33927	33928	33929	33975	33976	33977	33978	33979	33980
33981	33982	33983	93750	L8698	Q0477	Q0478	Q0479	Q0480
Q0481	Q0482	Q0483	Q0484	Q0485	Q0486	Q0487	Q0488	Q0489
Q0490	Q0491	Q0492	Q0493	Q0494	Q0495	Q0496	Q0497	Q0498
Q0499	Q0500	Q0501	Q0502	Q0503	Q0504	Q0506	Q0507	Q0508
Q0509								

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, unspecified
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) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure

ICD-10-CM Diagnosis Codes	Description
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
I50.9	Heart failure, unspecified
I97.0	Postcardiotomy syndrome

IX. REFERENCES

TOP

1. *Martin SS, Aday AW, Almarzooq ZI, et al. 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. Circulation. Feb 20 2024; 149(8): e347-e913. PMID 38264914*
2. *Lewsey SC, Breathett K. Racial and ethnic disparities in heart failure: current state and future directions. Curr Opin Cardiol. May 01 2021; 36(3): 320-328. PMID 33741769*
3. *Organ Procurement and Transplantation Network. National Heart Patient and Graft Survival as of June 21, 2024*
4. *Abbott/Thoratec Corp. Recalls HeartMate II and HeartMate 3 Left Ventricular Assist System (LVAS) due to Long-term Buildup Causing an Obstruction. U.S. Food & Drug Administration website. Updated April 15, 2024*
5. *TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11;Tab 26*
6. *Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. N Engl J Med. Nov 19 1998; 339(21): 1522-33. PMID 9819452*
7. *Mehra MR, Uriel N, Naka Y, et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. N Engl J Med. Apr 25 2019; 380(17): 1618-1627. PMID 30883052*
8. *Colombo PC, Mehra MR, Goldstein DJ, et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. Circulation. Jan 08 2019; 139(2): 155-168. PMID 30586698*
9. *Cowger JA, Naka Y, Aaronson KD, 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. Jan 2018; 37(1): 15-24. PMID 29153637*
10. *Goldstein DJ, Naka Y, Horstmanshof D, et al. Association of Clinical Outcomes With Left Ventricular Assist Device Use by Bridge to Transplant or Destination Therapy Intent: The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) Randomized Clinical Trial. JAMA Cardiol. Apr 01 2020; 5(4): 411-419. PMID 31939996*
11. *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): 675-83. PMID 23796152*

12. *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): 1375-82. PMID 21414534*
13. *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): 1247-54. PMID 11955839*
14. *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. 2007; 34(3): 275-81. PMID 17948075*
15. *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): 1227-34; discussion 1234-5. PMID 18805167*
16. *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): 885-96. PMID 17761592*
17. *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): 832-40; discussion 832-40. PMID 18721570*
18. *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): 289-94. PMID 18571932*
19. *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): 1065-72. PMID 18926395*
20. *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. Jan 01 2018; 53(1): 170-177. PMID 28950304*
21. *Schmitto JD, 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. Jan 2019; 21(1): 90-97. PMID 30052304*
22. *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. Oct 01 2018; 39(37): 3454-3460. PMID 30165521*
23. *Pagani FD, Mehra MR, Cowger JA, et al. Clinical outcomes and healthcare expenditures in the real world with left ventricular assist devices - The CLEAR-LVAD study. J Heart Lung Transplant. May 2021; 40(5): 323-333. PMID 33744086*
24. *Mehra MR, Cleveland JC, Uriel N, et al. Primary results of long-term outcomes in the MOMENTUM 3 pivotal trial and continued access protocol study phase: a study of 2200 HeartMate 3 left ventricular assist device implants. Eur J Heart Fail. Aug 2021; 23(8): 1392-1400. PMID 33932272*
25. *TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.*
26. *Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med. Nov 15 2001; 345(20): 1435-43. PMID 11794191*
27. *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*

28. *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): 133-8. PMID 15947534*
29. *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*
30. *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*
31. *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*
32. *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 06 2014; 63(17): 1751-7. PMID 24613333*
33. *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): 741-7. PMID 17707178*
34. *Arnold SV, Jones PG, Allen LA, et al. Frequency of Poor Outcome (Death or Poor Quality of Life) After Left Ventricular Assist Device for Destination Therapy: Results From the INTERMACS Registry. Circ Heart Fail. Aug 2016; 9(8). PMID 27507111*
35. *Mehra MR, Goldstein DJ, Cleveland JC, et al. Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial. JAMA. Sep 27 2022; 328(12): 1233-1242. PMID 36074476*
36. *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): 1871-80. PMID 27102502*
37. *Wever-Pinzon O, Drakos SG, McKellar SH, et al. Cardiac Recovery During Long-Term Left Ventricular Assist Device Support. J Am Coll Cardiol. Oct 04 2016; 68(14): 1540-53. PMID 27687196*
38. *Topkara VK, Garan AR, Fine B, et al. Myocardial Recovery in Patients Receiving Contemporary Left Ventricular Assist Devices: Results From the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). Circ Heart Fail. Jul 2016; 9(7). PMID 27402861*
39. *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): 2497-505. PMID 17485581*
40. *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. Mar 2018; 11(3): e004628. PMID 29519902*
41. *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): 2388-442. PMID 18799522

42. *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*
43. *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): 2321-7. PMID 26912304*
44. *Fraser CD, Jaquiss RD, Rosenthal DN, et al. Prospective trial of a pediatric ventricular assist device. N Engl J Med. Aug 09 2012; 367(6): 532-41. PMID 22873533*
45. *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): 578-84. PMID 27009673*
46. *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): 1702-11. PMID 23538380*
47. *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 22 2015; 4(1): e001429. PMID 25613996*
48. *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): 163-8. PMID 26720740*
49. *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): 603-9. PMID 27009672*
50. *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): 327-36; discussion 336-8. PMID 7677462*
51. *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): 1369-74; discussion 1375. PMID 10881807*
52. *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*
53. *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): 785-95. PMID 21551162*
54. *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): 224-8. PMID 23954004*
55. *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): 102-8. PMID 27068177*

56. *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): 421-7, 427.e1. PMID 18242279*
57. *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): 859-67. PMID 15329423*
58. *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): 727-34. PMID 22245242*
59. *Food and Drug Administration. Summary of Safety and Probable Benefit - H040006: AbioCor Implantable Replacement Heart. 2006*
60. *Dowling RD, Gray LA, Etoch SW, et al. Initial experience with the AbioCor implantable replacement heart system. J Thorac Cardiovasc Surg. Jan 2004; 127(1): 131-41. PMID 147524230*
61. *Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. ASAIO J. Nov-Dec 2014; 60(6): 626-34. PMID 25158888*
62. *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. Mar 2020; 39(3): 187-219. PMID 31983666*
63. *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. Aug 08 2017; 136(6): e137-e161. PMID 28455343*
64. *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*
65. *Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. May 03 2022; 145(18): e876-e894. PMID 35363500*
66. *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): 2648-67. PMID 23109468*
67. *Bernhardt AM, Copeland H, Deswal A, et al. The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support. J Heart Lung Transplant. Apr 2023; 42(4): e1-e64. PMID 36805198*
68. *Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). 2013;*
69. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.03.11, Total Artificial Hearts and Implantable Ventricular Assist Devices. September 2024*

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

X. POLICY HISTORY

TOP

MP 1.026	**08/18/2020 Consensus Review.** No change to policy statements. Coding reviewed and added diagnosis codes: I50.2, I50.3, I50.4, I50.9. References reviewed, updated. Product Variation Statement updated.

	09/08/2021 Minor Review. Removed previous criteria for Destination Therapy and added:
	• New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV;
	• Left ventricular ejection fraction ≤ 25%;
	• Inotrope-dependent; OR cardiac index <2.2 liters/min/m^2, while not on inotropes and also meeting one of the following:
	  ○ On optimal medical management, based on current heart failure practice guidelines for at least 45 of the last 60 days and are failing to respond OR
	  ○ Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.
	Under Policy Guidelines, added "The intent of treatment may evolve over the course of treatment; for example, there is not necessarily a strict delineation between bridge to transplant and destination therapy." Updated FEP variation language. Background, Rationale and Coding updated. References added.

	12/02/2021 Administrative Update. Removed deleted codes 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, 0462T, 0463T.
	11/29/2022 Consensus Review. No change to policy statement. Product variation language updated. Background, Rationale and References updated. Added ICD10 codes I50.810-I50.812**.**
	09/28/2023 Consensus Review. No change to policy statement. Policy reformatted. Policy Guidelines updated. References added. CPT codes 33981, 33982, 33983 added.
	10/18/2024 Consensus Review. No change to policy statement. Policy Guidelines, Background and References updated.
	10/7/2025 Policy retired.

TOP