

MEDICAL POLICY

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

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|------------------|---|
| CLINICAL BENEFIT | <input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| Effective Date: | 5/1/2025 |

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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 $\leq 25\%$; **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**

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- 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

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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

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II. PRODUCT VARIATIONS

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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

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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

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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 cardiectomy 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 |
|--------|--------------|---------------|---------------|-------------------------|------------|
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| 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:

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 |

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| Jarvik Total Artificial Heart) | | | | | biventricular failure. |
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IV. RATIONALE

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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.

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V. DEFINITIONS

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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

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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

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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

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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.

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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 failure |
| 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 |

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| ICD-10-CM Diagnosis Codes | Description |
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| 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

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X. POLICY HISTORY

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| 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: <ul style="list-style-type: none"> • New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV; • Left ventricular ejection fraction $\leq 25\%$; • Inotrope-dependent; OR cardiac index <2.2 liters/min/m², while not on inotropes and also meeting one of the following: <ul style="list-style-type: none"> ○ 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. |

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