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FEP Medical Policy Manual

FEP 7.03.11 Total Artificial Hearts and Implantable Ventricular Assist Devices

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Related Policies:

7.03.08 - Heart/Lung Transplant
7.03.09 - Heart Transplant

Total Artificial Hearts and Implantable Ventricular Assist Devices

Description

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether ventricular assist devices and total artificial hearts improve the net health outcome in individuals with end-stage heart failure or cardiogenic shock.

POLICY STATEMENT

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;
- 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.

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
- 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 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 ventricular assist devices (VADs) or total artificial hearts (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 VADs or TAHs is considered **investigational**.

Percutaneous VADs are considered **investigational** for all 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 ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. For example, the Berlin Heart EXCOR Pediatric VAD has FDA approval through the humanitarian device exemption process. This device 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. As of April 15 2024, the HeartMate 3 devices are under a Class I FDA recall due to the accumulation of biological material within the device - a serious complication that can lead to obstruction, posing significant risks of severe injury or death. In April 2025, Abbott removed HeartMate Mobile Power Unit (used with HeartMate II and HeartMate 3) due to instances of sudden power loss.

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 (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 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 7.03.09 (heart transplantation) 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.”

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of implantable ventricular assist devices (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 left VADs.

- The DeBakey VAD Child received FDA Humanitarian Device Exemption (HDE) approval in 2004, offering a temporary lifeline for pediatric patients with end-stage heart failure as they awaited heart transplantation. However, this device was replaced by the HeartAssist 5 VAD which is not currently available for use as it was an investigational device that was discontinued.
- As of April 15, 2024, both the HeartMate II and HeartMate 3 devices have been placed under a Class I FDA recall in response to the accumulation of biological material within the devices, an issue that can result in serious obstructions and significantly increase the risk of severe injury or death. In April 2025, Abbott further removed the HeartMate Mobile Power Unit, which is used with both the HeartMate II and HeartMate 3, following reports of sudden and unexpected power loss.[5,]
- The Abbott CentriMag Circulatory Support System received FDA approval in 2019 to provide longer-term life support to critically ill patients. In 2023, it was approved for longer-term use in adults when extracorporeal membrane oxygenation.[6,]

Table 1. Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
HeartMate II	Thoratec (Abbott)	Apr 2008	PMA	P060040	Bridge to transplant and destination
CentriMag	Thoratec (Abbott)	Dec 2019	PMA	P170038	Postcardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	PMA	P160035	Bridge to transplant or recovery
HeartMate 3 Left Ventricular Assist System	Thoratec (Abbott)	Aug 2017 Oct 2018	PMA PMA	P160054 P160054/S008	Bridge to transplant and destination

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

Total Artificial Heart

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 Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

Percutaneous Ventricular Assist Devices

Some circulatory assist devices are placed percutaneously (i.e., are not implanted). They may be referred to as percutaneous VADs (pVADs). Two different pVADs have been developed, the TandemHeart and the Impella device (Table 3).

In the TandemHeart System, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. LivaNova, the company that acquired CardiacAssist Inc. (the original developer of the TandemHeart), announced plans to wind down its Advanced Circulatory Support business, including the TandemHeart, in 2024. However, it is possible that some components, such as cannulas, may still be available for purchase.[7,]

The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. As of June 5, 2023, the FDA has issued a Class I recall for specific Impella 5.5 devices due to purge fluid leaks.[8,] On October 10, 2025, the FDA issued an alert on the automated Impella controller correction due to a cybersecurity issue.[9,]

Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

Table 3. Available Percutaneous Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, 510(k) No.	Indication
TandemHeart	Cardiac Assist (LivaNova)	Sep 2011	510(k)	K110493	Temporary left ventricular bypass of ≤6 h
Impella CP	Abiomed	Nov 2016	PMA	P140003	• Temporary (≤6 hours) ventricular support devices indicated for use during high-risk PCI • Temporary ventricular support for ≤4 days in cardiogenic shock
Impella 5.5	Abiomed	Nov 2016	PMA	P140003	Temporary ventricular support for ≤14 days in cardiogenic shock

FDA: U.S. Food and Drug Administration; PCI: percutaneous coronary intervention; PMA: premarket approval.

RATIONALE

Summary of Evidence

Ventricular Assist Device

For individuals who have end-stage heart failure who receive a ventricular assist device (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 (OS), 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 OS, symptoms, functional outcomes, QOL, 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 total artificial heart (TAH) as a bridge to transplant, the evidence includes case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, 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 OS, symptoms, functional outcomes, QOL, 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.

Percutaneous Ventricular Assist Device

For individuals with cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes RCTs, observational studies, and a systematic review. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. A meta-analysis of four RCTs found pVAD use in AMI-related cardiogenic shock reduced 6-month mortality but not 30-day mortality. pVADs were associated with significantly increased risks of major bleeding, limb ischemia, and sepsis, with no improvement in left ventricular ejection fraction compared to standard care. Comparative observational studies and a long-term follow-up study were consistent with the RCT evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes RCTs, observational studies, and systematic reviews of these trials. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. RCTs , controlled and uncontrolled observational studies, and systematic reviews of these studies have generally not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. Additionally, 2 nonrandomized studies have compared ventricular tachycardia (VT) ablation with pVAD or IABP. Both studies demonstrated that patients who had pVAD support spent less time in unstable VT than patients without pVAD support. However, the current evidence does not support conclusions about the use of pVAD for VT ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cardiogenic shock refractory to IABP therapy who receive a pVAD, the evidence includes case series. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Thoracic Surgery et al

In 2020, the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation published guidelines on selected topics in mechanical circulatory support (MCS), including recommendations on the use of pVADs (Table 4).[78,] The guideline authors noted, "Compared with IABP [intraaortic balloon pump], contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

Table 4. 2020 Guidelines on Mechanical Circulatory Support

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

COE: class of evidence; LOE: level of evidence; LV: left ventricular.

American College of Cardiology Foundation et al

In 2017, the American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA.[79,] Left ventricular assist device was 1 of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after guideline-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then a left ventricular assist device would be an additional treatment option.

The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged. The American College of Cardiology Foundation and AHA (2013) released guidelines for the management of heart failure that included recommendations related to the use of MCS , including both durable and nondurable MCS devices.[80,] The guidelines categorized pVADs and extracorporeal ventricular assist devices (VADs) as nondurable MCS devices. Since the 2017 update, these guidelines have been updated regularly, with the most recent update occurring in 2022.[81,] Table 5 provides recommendations on MCS devices from the most recently updated guideline iteration.

Table 5. AHA/ACC/HFSA Guidelines on Mechanical Circulatory Support

Recommendation	COE[a]	LOE[b]
"In select patients with advanced HFrEF with NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, QOL, and survival."	I	A

"In select patients with advanced HFrEF who have NYHA class IV symptoms despite GDMT, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality."	IIA	B-R
"In patients with advanced HFrEF and hemodynamic compromise and shock, temporary MCS, including percutaneous and extracorporeal ventricular assist devices, are reasonable as a 'bridge to recovery' or 'bridge to decision'"	IIA	B-NR

ACC: American College of Cardiology; AHA: American Heart Association; COE: class of evidence; GDMT: guideline-directed medical therapy; HF*r*EF: heart failure with reduced ejection fraction; HFSA: Heart Failure Society of America; LOE: level of evidence; LVAD: left ventricular assist device; MCS: mechanical circulatory support; NYHA: New York Heart Association; QOL: quality of life; RCT: randomized controlled trial.

[a]I: Strong; IIa: Moderate.

[b]A: high quality evidence from more than 1 RCT; B-R: Moderate-quality evidence from 1 or more RCTs; B-NR: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies.

American Heart Association

In 2012, the AHA published recommendations for the use of MCS.[82,] These guidelines defined nondurable MCS as IABPs, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 6 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 6. 2012 Guidelines on Mechanical Circulatory Support

Recommendation	COE	LOE
"MCS for BTT indication should be considered for transplant-eligible patients with end-stage HF who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation."	I	B
"Implantation of MCS in patients before the development of advanced HF ... is associated with better outcomes. Therefore, early referral of HF patients is reasonable."	IIA	B
"MCS with a durable, implantable device for permanent therapy or DT is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation."	I	B
"Elective rather than urgent implantation of DT can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies."	IIA	C
"Urgent nondurable MCS is reasonable in hemodynamically compromised HF patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile." "These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	IIA I	C C
"Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS."	IIA	B

BTT: bridge to transplant; COE: class of evidence; DT: destination therapy; HF: heart failure; LOE: level of evidence; MCS: mechanical circulatory support.

International Society for Heart and Lung Transplantation

The International Society for Heart and Lung Transplantation and the Heart Failure Society of America released a guideline on acute MCS in 2023.[83,] The guideline focuses on timing, patient and device selection of acute MCS, and periprocedural and postprocedural care for cardiogenic and pulmonary shock. They provide specific recommendations depending on which MCS device is chosen. Table 7 summarizes relevant recommendations for timing of acute MCS made in the guidelines. Additional recommendations related to specific devices is related to procedural considerations.

Table 7. ISHLT/HFSA Guideline on Acute Mechanical Circulatory Support

Recommendation	COR	LOE
"Acute MCS should be initiated as soon as possible in patients with CS who fail to stabilize or continue to deteriorate despite initial interventions."	I	B
"The use of acute MCS should be considered in patients with multiorgan failure to allow successful optimization of clinical status and neurologic assessment before placement of durable MCS or organ transplantation."	II	C

COR: class of recommendation; CS: cardiogenic shock; HFSA: Heart Failure Society of America; ISHLT: International Society for Heart and Lung Transplantation; LOE: level of evidence; MCS: mechanical circulatory support

Society for Cardiovascular Angiography and Interventions et al

In 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America, the Society of Thoracic Surgeons, and the American College of Cardiology published a joint clinical expert consensus statement on the use of percutaneous MCS devices in cardiovascular care.[84,] This statement addressed IABPs, left atrial-to-aorta assist device (eg, TandemHeart), left ventricle-to-aorta assist devices (eg, Impella), extracorporeal membrane oxygenation, and methods of right-sided support. Specific recommendations were not made, but the statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention, those with cardiogenic shock, and those with acute decompensated heart failure.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for VADs.[85,] The NCD mandates coverage for VADs for the following indications:

- For support of blood circulation in the post cardiotomy setting, defined as the period following open-heart surgery.
    - If the VAD has U.S. Food and Drug Administration (FDA) approval for that purpose and are used according to the FDA-labeled indication
- For short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for patients who meet the following criteria:
    - Have New York Heart Association (NYHA) Class IV heart failure; and
    - Have a left ventricular ejection fraction (LVEF) ≤25%; and
    - Are inotrope dependent

      OR

      have a cardiac index <2.2 L/min/m2, while not on inotropes, and also meet 1 of the following:
        - Are on optimal medical management, based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; OR
        - Have advanced heart failure for at least 14 days and are dependent on an IABP or similar temporary mechanical circulatory support for at least 7 days.

"Beneficiaries receiving VADs for DT [destination therapy] must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience.... 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."

"Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services."

Effective December 1, 2020, Artificial Hearts has been removed from the NCD Manual. Coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
December 2014	Replace policy	Policy updated with a literature review, adding references 5, 6, 20, 21, 24, 27, 28, 40-44, 47, 49, 50 & 51 and deleting others. Policy updated to include total artificial hearts as medically necessary as a bridge to transplant for patients with biventricular failure until a donor can be obtained. The policy name was revised to add Total Artificial Hearts.
March 2016	Replace policy	Policy updated with literature review through April 21, 2015; references 7-8, 27, 32, 38, 41, 50, 55, 57, 61-62, 65-66, and 70 added. Policy statements unchanged.
March 2018	Archive policy	Policy updated with literature review through July 22, 2017; references 5-7, 34, 47, 49-51, 70, 72, 83, 85, 88, and 93 added. Policy statements were reordered; wording of statements unchanged. Policy archived.
June 2019	Reactivate policy	Policy updated with literature review through June 21, 2018; several references added. Policy statements unchanged. Policy reactivated.
December 2019	Replace policy	Policy updated with literature review through June 10, 2019; references added. Regulatory Status section updated with HeartMate 3 indication for destination therapy. Policy statements unchanged except pVAD statement corrected to "not medically necessary" due to FDA PMA of Impella System.
December 2020	Replace policy	Policy updated with literature review through June 29, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through June 28, 2021; references added. Evidence review revised substantially to increase clarity. Medicare National Coverage section updated. Policy statement revised to remove outdated eligibility criteria, but intent unchanged.
December 2022	Replace policy	Policy updated with literature review through June 22, 2022; references added and updated. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through June 20, 2023; references added. Editorial refinements to policy statements for clarity; intent unchanged.
December 2024	Replace policy	Policy updated with literature review through June 24, 2024; references added. Policy statements unchanged.
March 2026	Replace policy	Policy updated with literature review through August 25, 2025; references added. Studies focused on ventricular assist devices (HeartWare, Novacor) that have been discontinued and lack any available upgrades has been excluded from the Rationale section. Policy statements unchanged.