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MEDICAL POLICY – 7.03.11

Total Artificial Hearts and Implantable Ventricular Assist Devices

BCBSA Ref. Policy:	7.03.11
Effective Date:	Nov. 1, 2024
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.03.08	Heart/Lung Transplant
7.03.09	Heart Transplant

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

An implantable ventricular assist device (VAD) is a battery-operated mechanical pump that can help your heart pump blood out to the rest of your body. The VAD is surgically put in your body. It has a tube that pulls blood from the left ventricle (the main pumping chamber of the heart) and pumps the blood into the aorta (the main artery leaving the heart). The blood is then sent out to the rest of the body. Another device, called a total artificial heart (TAH), can be implanted in the chest to replace both lower pumping chambers in the heart. This policy identifies the criteria needed for a VAD or TAH to be covered as medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity
Bridge to Transplantation (Short-Term Devices)	
Implantable ventricular assist devices (VADs) with FDA approval	**US Food and Drug Administration (FDA) approved ventricular assist devices (VADs) may be considered medically necessary as a bridge to heart transplantation for adult and pediatric (see Related Information) individuals:** • Who are currently listed as heart transplantation candidates and are not expected to survive until a donor heart can be obtained, **OR** • Who are undergoing evaluation to determine candidacy for heart transplantation
Total artificial hearts (TAHs) with FDA-approval	**US Food and Drug Administration (FDA) approved total artificial hearts (TAHs) implantation may be considered medically necessary as a bridge to heart transplantation for individuals with ALL the following:** • Biventricular failure who have no other reasonable medical or surgical treatment options **AND** • Are ineligible for other univentricular or biventricular support devices, **AND** • Are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation **AND** • Are not expected to survive until a donor heart can be obtained
Destination Therapy (Long-Term Devices)	
Implantable VADs with FDA approval	**US Food and Drug Administration (FDA) approved implantable VADs may be considered medically necessary as destination therapy for adult individual with end-stage heart failure who meet ALL the following criteria:** • New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV (See **Related Information**), **AND** • Left ventricular ejection fraction ≤ 25%,

Device	Medical Necessity
	AND • Inotrope-dependent; **OR** • Cardiac index < 2.2 liters/min/m², while not on inotropes and also meeting one of the following: ○ Failed to respond to optimal medical management, based on current heart failure practice guidelines (e.g., beta-blockers and angiotensin-converting enzyme [ACE] inhibitors) for at least 45 of the last 60 days **OR** ○ Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥ 7 days
Postcardiotomy Setting/Bridge to Recovery	
Implantable VADs with FDA approval	**FDA approved implantable VADs may be considered medically necessary in individuals who are postcardiotomy (following open-heart surgery) and are unable to be weaned off cardiopulmonary bypass.**

Device	Investigational
Other applications of VADs or TAHs	**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 implantable VADs or TAHs is considered investigational.** **Percutaneous VADs are considered investigational for all indications. (e.g., TandemHeart, Impella 2.5, Impella 5.0 System, Impella 5.5)**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met.

Documentation Requirements

For implantable ventricular assist devices (VADs) as bridge therapy for adult and pediatric individuals, the record should include clinical documentation that:

- Individual is currently listed as a heart transplant candidate, but a heart is not yet available, and individual's own heart may not be able to keep the individual alive until one is found

OR

- It's used during the evaluation to see if individual is a candidate for a heart transplant

For total artificial hearts (TAHs) with FDA-approval–bridge therapy, the record should include clinical documentation of ALL the following:

- Individual's heart failure affects both sides of the heart and there are no other reasonable medical or surgical treatment options

AND

- Individual is ineligible for any other support devices

AND

- Individual is waiting for a donor heart or being evaluated for a donor heart

AND

- Individual is not expected to survive until a donor heart can be obtained

For implantable VADs with FDA approval– destination therapy for adult individuals with end stage heart failure, the record should include clinical documentation of ALL the following:

- 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:
  - Failed to respond to optimal medical management, based on current heart failure practice guidelines (e.g., beta-blockers and angiotensin-converting enzyme [ACE] inhibitors) for at least 45 of the last 60 days

  OR

  - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥ 7 days

For implantable VADs with FDA approval – postcardiotomy, the record should include clinical documentation that:

Documentation Requirements
• Individual had an open-heart surgery and is unable to be weaned off cardiopulmonary bypass

Coding

Code	Description
CPT	
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.

Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.

Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound individuals

Only 2 ventricular assist devices (VADs) have approval from the US 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 process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant (i.e., 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. See **Regulatory Status** and **Ongoing and Unpublished Clinical Trials** sections below.

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 days 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 Related Policies) for further discussion of heart transplant candidacy.

Evidence Review

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.

Background

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.[1] 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).[2] Similar findings were demonstrated in the Atherosclerosis Risk in Communities 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 several etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is 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.[3] The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Treatment

Ventricular Assist Devices

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

Surgically implanted VADs represent a method of providing mechanical circulatory support for individuals 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 individual 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.

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.

Percutaneous VADs

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. 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. 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. 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 the 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.

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, 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 individuals with end-stage heart failure, possibly reducing mortality as well as improving QOL. These studies have reported that substantial numbers of individuals have survived 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, QOL, and treatment-related mortality and morbidity. A well-designed trial, with two years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for individuals ineligible for heart transplant. Despite an increase in adverse events, both mortality and QOL appear to be improved for these individuals. A more recent trial comparing VADs has broader inclusion criteria and supports those 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, 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 individuals 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, 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 (pVAD), the evidence includes RCTs, observational studies, and a systematic review. Relevant outcomes are overall survival (OS), symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD versus intra-aortic balloon pump for individuals in cardiogenic

shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. 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. Randomized controlled trials, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for individuals undergoing high-risk cardiac procedures. Additionally, 2 nonrandomized studies have compared ventricular tachycardia (VT) ablation with pVAD or IABP. Both studies demonstrated that individuals who had pVAD support spent less time in unstable VT than individuals 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 intra-aortic balloon pump therapy (IABP) who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01633502	Effects of Advanced Mechanical Circulatory Support in Patients with ST Segment Elevation Myocardial Infarction Complicated by Cardiogenic Shock. The Danish Cardiogenic Shock Trial	360	Jan 2024
NCT01627821[a]	Evaluation of the Jarvik 2000 Left Ventricular Assist System with Post-Auricular Connector--Destination Therapy Study	350	Mar 2025
NCT02232659	SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT)	38	May 2022
NCT01187368[a]	Prospective Multi-Center Randomized Study for Evaluating the EVAHEART2 Left Ventricular Assist System: the COMPETENCE Trial	399	Mar 2024
NCT02387112	Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation	102	Dec 2024
NCT04768322	Left Ventricular Assist Device (LVAD) Versus Guideline Recommended Medical Therapy in Ambulatory Advanced Heart Failure Patients (GDMT)	92	Feb 2027
Unpublished			
NCT02326402	THEME Registry: TandemHeart Experiences and Methods	365	Jan 2023

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from two physician specialty societies and five academic medical centers while this policy was under review in 2014. Vetting focused on the use of percutaneous ventricular assist devices (pVADs) under the American Heart Association and

American College of Cardiology guidelines (2013) and on the use of total artificial heart as destination therapy. All providing input supported the use of implantable ventricular assist devices as destination therapy subject to the guidelines in the policy statements. Most providing input considered total artificial hearts to be investigational for destination therapy; reviewers noted that there are limited clinical trial data to support the use of total artificial hearts as destination therapy.

Most providing input considered pVADs to be investigational as a "bridge to recovery" or "bridge to decision" and for all other indications. Some reviewers noted that pVADs may improve patients' hemodynamics better than other alternatives, such as an intra-aortic balloon pump, but are associated with more complications. Some noted that, despite a lack of evidence to indicate that pVADs improve overall outcomes, there may be cases when pVADs may be considered to support an intervention or treatment for a life-threatening condition.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a United States (US) professional society, an international society with US representation, or National Institute for Health and Care Excellence. 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/International Society for Heart and Lung Transplantation

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, including recommendations on the use of pVADs (**Table 2**).[83],The guideline authors noted, "Compared with intra-aortic balloon pump (IABP), contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

Table 2. 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.

The American College of Cardiology Foundation et al

In 2017, the American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of America published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA.[84] Left ventricular assist device was one of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after 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 mechanical circulatory support (MCS), including both durable and nondurable MCS devices.[85] The guidelines categorized percutaneous ventricular assist devices (pVADs) and extracorporeal VADs as nondurable MCS devices. Since the 2017 update, these guidelines have been updated regularly, with the most recent update occurring in 2022.[86] **Table 3** provides recommendations on MCS devices from the most recently updated guideline iteration.

Table 3. AHA/ACC/HFSA Guidelines on Mechanical Circulatory Support (MCS)

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

Recommendation	COE[a]	LOE[b]
"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; HFrEF: 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 (AHA)

In 2012, the AHA published recommendations for the use of MCS.[87] These guidelines defined nondurable MCS as intra-aortic balloon pumps (IABPs), extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. **Table 4** lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 4. 2012 Guidelines on Mechanical Circulatory Support (MCS)

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

Recommendation	COE	LOE
"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."	IIA	C
"These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	I	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.[88] 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 5** summarizes relevant recommendations for timing of acute MCS made in the guidelines. Additional recommendations related to specific devices is related to procedural considerations.

Table 5. ISHLT/HFSA Guideline on Acute MCS

Recommendation	COE	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 mechanical circulatory support (MCS) devices in cardiovascular care.[89] This statement addressed intra-aortic balloon pumps, left atrial-to-aorta assist devices (e.g., TandemHeart), left ventricle-to-aorta assist devices (e.g., 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.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for VADS.[90] 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 US 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 individuals 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 (CI) < 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.

Regulatory Status

A number of implantable ventricular assist devices (VADs) and artificial heart systems have been (FDA) approved through a Humanitarian Device Exemption, 510(k), or premarket approval regulatory pathway. These devices are summarized in **Table 6** and **Table 7**. The FDA maintains a list of recent device recalls at: **https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls** Last accessed September 5, 2024.

Table 5 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 ventricular assist devices.

Table 6. Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
VADs					
Thoratec IVAD	Thoratec	Aug 2004	PMA supplement	P870072	Bridge to transplant and postcardiotomy
DeBakey VAD Child	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE, or 510(k) No.	Indication
					children 5-16 y of age
HeartMate II	Thoratec	Apr 2008	PMA	P060040	Bridge to transplant and destination
CentriMag	Levitronix (now Thoratec)	Dec 2019	HDE	P170038	Postcardiotomy
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	HDE	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; VAD: ventricular assist device.

Table 7. 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.

Currently the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (**Table 7**). 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.

Percutaneous Ventricular Assist Devices (VADs)

Table 8. Available Percutaneous Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, 510(k) No.	Indication
TandemHeart	Cardiac Assist	Sep 2011	510(k)	K110493	Temporary left ventricular bypass of ≤6 h
Impella Recover LP 2.5	Abiomed	May 2008	510(k)	K063723	Partial circulatory support using extracorporeal bypass control unit for ≤6 h
Impella 2.5 System	Abiomed	Mar 2015	PMA	P140003	Temporary ventricular support for ≤6 h

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

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History

Date	Comments
04/14/98	Add to Surgery Section - New Policy
06/01/99	Replace policy - Policy updated to include new FDA-approved devices.
06/27/00	Replace policy - Scheduled review; no criteria changes.
11/12/02	Replace policy - Policy reviewed: Rationale section expanded; references added. Policy statement on use of VADs in patients who are not transplant candidates deleted; this topic will be addressed in a separate policy. Policy statement otherwise unchanged.
04/15/03	Replace policy - Policy statement revised to include 2002 TEC Assessment conclusions regarding VADs in patients who are not transplant candidates, i.e., "destination" therapy. Title changed from Ventricular Assist Devices as a Bridge to Heart Transplantation.
10/16/03	Replace policy - Policy statement revised to limit medically necessary indications to FDA approved devices.
02/10/04	Replace policy - Policy statement added regarding investigational status of total artificial hearts. Additional 2003 Category III CPT codes added.
06/14/05	Replace policy - Policy statement revised to indicate that a total artificial heart may be considered medically necessary as a bridge to transplant, based on FDA approval for that indication.

Date	Comments
04/21/06	Codes Updated - No other changes
05/26/06	Scope and Disclaimer Updates - No other changes.
07/11/06	Replace policy - Policy updated with literature review; references added; policy statement unchanged.
11/14/06	Replace policy - Policy updated with FDA approval of total artificial heart. Policy statement unchanged; total artificial hearts are investigational. References added.
12/11/06	Codes Updated - No other changes
10/14/08	Replace policy - Policy updated with literature search, no change to the policy statement. Codes 37.52-37.66 added, references added.
10/13/09	Replace policy - Policy updated with literature search, no change to the policy statement. References added.
02/09/10	Codes Update - New 2010 codes added.
11/09/10	Replace policy - Policy updated with literature search; references 1, 10, 19, 29 and 30 added. Extensive editing completed. Policy statements revised to address only implantable VADs and total artificial hearts.
10/11/11	Replace policy – Policy updated with literature search. Percutaneous VADs, previously not addressed, added to policy statement as investigational. Rationale updated. References 22, 30-39, 42, 43 added. ICD-10 codes added to policy.
11/27/12	Replace policy - Policy updated with literature search. References 18, 27-31, 33, 40, 47. Clause added to policy statement on TAH that says "…or are undergoing evaluation to determine candidacy for heart transplantation…"
01/10/13	Coding update. CPT codes 0148T – 0150T deleted as of 12/31/12; codes 33990 – 33991 and 33993, effective 1/1/13, added to policy.
04/08/13	Replace policy. Policy statement on children amended; age range changed from 5-16 to 0-16, reflecting the approval of the BERLIN heart EXCOR device for pediatric patients aged 0-16. Code Q0505, deleted 3/13/13; this is replaced with Q0507-Q0509, new codes 4/1/13.
03/11/14	Coding Update. Codes 37.52 - 37.55, 37.55, 37.60, and 37.62 - 37.66 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.
07/31/14	Annual Review. Policy updated with literature review through January, 2014 and results of clinical vetting related to the use of pVADs and the total artificial heart (TAH) as destination therapy. References 5, 6, 20, 23, 24, 27, 55 added; others renumbered/removed. Policy statements unchanged.
07/14/15	Annual Review. 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. Coding update: CPT codes 33977, 33978, 33980, 33981, 33982, 33983 and 93750, plus HCPCS Q0506 removed; they were informational only.

Date	Comments
11/01/16	Annual Review, approved October 11, 2016. Policy revised to remove all information regarding total artificial hearts and -implantable ventricular assist devices, including removing previous references 1-56 and policy title change. Policy now addresses only percutaneous ventricular assist devices. Policy updated with literature review but no change to the policy statement regarding pVADs, which remain investigational.
11/01/17	Annual review approved October 10, 2017. 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 revised to add information regarding total artificial hearts and implantable ventricular assist devices. Codes updated; removed 33999 and added 0051T, 0052T, and 0053T.
03/03/18	Coding update: added note that CPT codes 0051T, 0052T, and 0053T were terminated 1/1/18. Added new CPT codes 33927, 33928, and 33929 (new codes effective 1/1/18).
11/01/18	Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; several references added. Other than minor editing for clarity, policy statements unchanged. Added CPT codes 33975, 33976, 33979, 33981, 33982, 33983.
01/01/19	Coding update, removed CPT codes 0051T, 0052T, and 0053T as they were terminated 1/1/18.
11/01/19	Annual Review, approved October 4, 2019. Policy updated with literature review through June 2019; references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020 and replaced with InterQual criteria for dates of service on or after July 2, 2020.
05/06/20	Interim Review, approved May 5, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
07/02/20	Coding update. Removed CPT's 33981, 33982, 33983, 33990, 33991, 33992, 33993.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through June 2020; references added. Policy statements unchanged. Added codes 33981, 33982, 33983, 33990, 33991, 33992, 33993.
12/01/20	Coding update, added new CPT codes 33995 & 33997 effective 1/1/2021.
11/01/21	Annual Review, approved October 12, 2021. Policy updated with literature review through June 28, 2021; references added. Policy statement for destination therapy revised to remove outdated eligibility criteria, but intent unchanged. Added CPT codes 0451T-0454T. Updates are effective for dates of service February 4, 2022, and after.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 22, 2022; references added and updated. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Date	Comments
11/01/23	Annual Review, approved October 9, 2023. Policy updated with literature review through June 20, 2023; references added. Editorial refinements to policy statements for clarity; intent unchanged.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 24, 2024; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.