MEDICAL POLICY

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Medical Policy Title	**Ventricular Assist Device (VAD) and Total Artificial Heart (TAH)**
Policy Number	**7.01.114**
Current Effective Date	**March 19, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Ventricular Assist Device (VAD)

I. VADs approved for use by the U.S. Food and Drug Administration (FDA) are considered **medically appropriate** for **ANY** of the following indications:

A. Bridge to transplant for individuals that meet **ALL** of the following criteria:

1. Diagnosed with severe ventricular heart failure;
2. Are approved as a heart transplant candidate by an approved heart transplant center;
3. Have an imminent risk of dying before donor heart procurement;
4. Are on optimal inotropic (influencing the contractility of muscular tissue) support;
5. Are on an intra-aortic balloon pump (IABP), unless contraindicated; **and**
6. Individual does not have **ANY** of the following contraindications for bridge to transplant:
   a. The individual has a condition that would generally exclude patients from heart transplant:
      i. Chronic irreversible hepatic, renal, or respiratory failure;
      ii. Systemic infection; **or**
      iii. Blood dyscrasia (non-specific term for any blood-related diseases).
   b. The individual has an uncorrected heart valvular disease.

B. Bridge to recovery for individuals that meet **EITHER** of the following indications:

1. Post-cardiotomy individuals who are unable to be weaned from cardiopulmonary bypass; **or**
2. Who have potentially reversible left ventricular dysfunction due to acute cardiogenic shock or acute myocarditis.

C. Destination therapy for adult individuals that meet **ALL** of the following criteria:

1. End-stage heart failure;
2. Have been determined to be ineligible for heart transplantation (e.g., smoking);
3. New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV;
4. Left ventricular ejection fraction ≤ 25%;
5. Have functional limitation, with a peak oxygen consumption of less than or equal to 14 ml/kg/min; (This criterion may be waived in persons who are balloon pump or intravenous inotrope dependent or are otherwise unable to perform exercise stress testing);
6. Are of appropriate body size to support the Left (VAD) implantation; **and**
7. Inotrope-dependent; **or** cardiac index <2.2 liters/min/m^2, while not on inotropes and also meeting **one** of the following:
    a. 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**
    b. Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for at least seven (7) days.

Percutaneous Ventricular Assist Device (pVAD)

II. pVAD approved for use by the FDA are considered **medically necessary** for **ANY** of the following indications:
    A. Individuals undergoing unprotected left main, high-risk percutaneous coronary intervention (PCI) and left ventricular ejection fraction (LVEF) less than or equal to 35%;
    B. Individual undergoing last remaining patent coronary vessel PCI with LVEF less than or equal to 35%;
    C. Individuals with three vessel disease and LVEF less than or equal to 30%;
    D. To provide short term circulatory support in cardiogenic shock.

Total Artificial Heart (TAH)

III. TAH approved for use by the FDA are considered **medically appropriate** for **ALL** of the following indications:
    A. As a Bridge to transplant;
    B. No other reasonable medical or surgical treatment options are available;
    C. Ineligible for other univentricular or biventricular support devices;
    D. Currently listed as a heart transplantation candidate or undergoing evaluation to determine candidacy for heart transplantation;
    E. At risk of imminent death from non-reversible biventricular heart failure until a donor heart

can be obtained.

IV. TAH as a destination therapy (permanent replacement for a human heart) is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.02.06 Heart and Heart/Lung Transplant

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The following guidelines may be used as hemodynamic selection criteria for bridge to transplant:

A. The patient has either a left atrial pressure of 20m Hg or a cardiac index of less than 2.0 L/min/m2;

B. The patient is generally being treated as an inpatient and has been categorized by the American Heart Association, or comparable, as Class IV CHF; and

C. The patient is classified as Status I by the United Network for Organ Sharing (considered the highest priority for transplantation).

II. Individuals considered for VAD implantation as destination therapy should be evaluated for potential difficulties that would complicate and diminish the success of the implantation, including an assessment of patient compliance.

DESCRIPTION

Bridging to Heart Transplantation

Bridging to heart transplantation involves improving hemodynamics and restoring organ function such that a patient may have a better probability of surviving until a donor heart is available.

Destination Therapy

Destination therapy is used for individuals with end-stage heart failure, who are not candidates for heart transplant and who are currently receiving optimal medical therapy with ACE inhibitors, beta-blockers, and inotropic drugs.

Bridge to Recovery

Bridge to recovery by a VAD is for patients with potentially reversible left ventricular dysfunction. Implantation of VADs provides circulatory support and allows myocardial recovery in post-cardiotomy cases where the patient cannot be weaned from cardiopulmonary bypass, and in patients with acute cardiogenic shock or acute myocarditis.

VAD

VADs fit into the general category of mechanical circulatory assist devices. VADs have been

developed to provide mechanical support for patients with severe heart failure who are awaiting a heart transplant (bridge to transplant), for patients with post-cardiotomy or potentially reversible left ventricular dysfunction (bridge to recovery), and, in certain specific instances, for patients with end-stage heart failure who are not suitable transplant candidates (destination therapy).

- The Heartmate II LVAD, a continuous flow device, received FDA approval as destination therapy and bridge to transplant for treatment of advanced-stage heart failure.
- The HeartMate 3 Left Ventricular Assist System is the only commercially-approved continuous flow implantable left ventricular assist system to utilize Full MagLev (fully magnetically-levitated) flow technology, which allows the device's rotor to be "suspended" by magnetic forces—rather than bearings—with the goal of being able to more gently pass the blood cells through the pump. This device should not be used in patients who cannot tolerate, or who are allergic to, anticoagulation therapy (blood thinners).
- HeartWare HVAD System was approved by the FDA for the use in destination therapy in patients with advanced heart failure who are not candidates for heart transplant. This system is contraindicated in patients who cannot tolerate anticoagulation therapy.
- MicroMed HeartAssist 5 is a ventricular assist device for home and hospital use, for children ages five to 16 years who are awaiting a heart transplant. Data showed that the device had a reasonable probability of being safe and effective in children.
- The Berlin Heart EXCOR Pediatric VAD has become the first pediatric-specific VAD that has gained widespread acceptance in North America. It is the only Pediatric VAD that can be used for newborns, infants and small children ≤ 25 kg.
- The DeBakey VAD Child (HeartAssist 5 pediatric VAD) has Humanitarian Device Exemption (HDE) authorization from the FDA for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (ages 5 to 16 years, with BSA greater than or equal to 0.7 m^2 and less than 1.5 m^2) who are in NYHA Class IV end-stage heart failure, are refractory to medical therapy, and are (listed) candidates for cardiac transplantation.

Percutaneous VAD

pVADs are not implanted through an open-heart surgical procedure, the device is kept outside the body and is connected to the heart via a thin tube that is inserted percutaneously (through the skin) into an artery or vein. Percutaneous VADs can provide temporary heart support following heart surgery, heart attack, or other heart injury that impairs the ability of the ventricles to pump blood.

- The Impella 2.5 provides partial circulatory support for periods up to six hours. Up to 2.4 liters of blood per minute are delivered by the pump from the left ventricle into the ascending aorta, providing the heart with active support in critical situations.

Total Artificial Heart

TAHs as a means to maintain heart function or to provide a bridge to heart transplantation have been developed to provide an option to patients in whom a left ventricular assist device (LVAD) or biventricular assist device may be contraindicated, including those with aortic regurgitation, cardiac

arrhythmias, a left ventricular thrombus, an aortic prosthesis, an acquired ventricular septal defect, or an irreversible biventricular failure requiring high pump outputs.

- The SynCardia t-TAH is a biventricular, pneumatic, pulsatile pump that serves as a total replacement for both ventricles of a heart. The SynCardia heart completely replaces the patient's native ventricles and all four cardiac valves. This device is intended as a temporary bridge to transplant and is removed at the time of transplantation. It is not intended for permanent use as a mechanical circulatory support system.

SUPPORTIVE LITERATURE

HeartMate II (Thoratec Corp.)

Estep et al (2015) reported the results of the ROADMAP study (Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients). It was a prospective observational study of 200 patients. The primary composite endpoint was survival on original therapy with improvement in 6-minute walk distance greater or equal to 75 meters at 12 months. They found that survival with improved functional status was better with the HeartMate II LVAD compared to optimal medical therapy and that despite more frequent adverse events. They support HeartMate II use in the functionally limited, noninotrope-dependent heart failure patients with health-related quality of life. Starling et al. (2017) conducted a study looking at the ROADMAP endpoints but extending it to 2 years. Results showed improvement in the 6-minute walk distance in patients with LVAD compared to optimal medical therapy. A reduction in adverse events were found after 1 year.

Jorde et al (2014) conducted a prospective post-approval study of the first 247 HeartMate II patients identified pre-operatively as eligible for destination therapy in the national INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) registry. A total of 133 patients from 34 centers were included in the primary data cohort in the destination therapy pivotal trial (TR). All survival rates and adverse events for the post-approval (PA) group were obtained from the INTERMACS registry. Patients with advanced heart failure who were ineligible for heart transplantation and were refractory to optimal medical management were considered for enrollment and had clinical follow-up after implantation for at least 2 years or until primary endpoint was met. Adverse events were similar or lower in the PA group than those in the TR group (including improvements in device-related infection and post operative bleeding requiring surgery). Kaplan-Meier survival at 2 years was 62% for the PA group vs 58% in the TR group. PA group survival at 1 and 2 years was 82 ± 5% and 69 ± 6% for INTERMACS profiles 4 to 7 (n =63) versus 72 ± 3% and 60 ± 4% for profiles 1 to 3 (n =184). The median length of stay after surgery was reduced by 6 days in the PA group versus the TR group.

Other studies have been completed such as PREVENT, a prospective, non-randomized, single arm, multi-center study. It looked at the prevention of HeartMate II pump thrombosis through clinical management. This study gives surgical and anticoagulation and anti-platelet, pump speed, and blood pressure management recommendations. The recommendations were adhered to during the study and was associated with a low incidence of early pulmonary thrombosis with the HeartMate II (Maltais et al., 2017).

HeartWare HVAD (Medtronic, Inc.)

Milano et al (2018) conducted a prospective multicenter Supplemental trial (ENDURANCE trial) that evaluated 465 patients with advanced heart failure that were ineligible for transplantation. The primary endpoint was the 12-month incidence of transient ischemic attack (TIA) or stroke with residual deficit 24 weeks post event. The secondary composite endpoint included free from death, disabling stroke, and need for device replacement or urgent transplant. They also compared stroke or TIA rates in HVAD cohorts in both the ENDURANCE and ENDURANCE Supplemental trial. The primary endpoint was not achieved. There was a higher incidence of neurological injury for the HVAD versus the control (HeartMateII). They did find that in the secondary composite endpoint, the HVAD System was superior to the control. They found that managing the blood pressure reduced the risk of stroke in the HVAD participants. They determined that the HVAD is safe and effective for patients' ineligible for cardiac transplant and reasonable as an alternative to eth HeartMateII.

HeartWare HVAD System was approved by the FDA for the use in destination therapy in patients with advanced heart failure who are not candidates for heart transplants based on results from the ENDURANCE trial, it was multicenter randomized trial involving 446 patients with advanced heart failure that were eligible for heart transplant. They were assigned in a 2:1 ratio to the centrifugal-flow device (study group) or the axial-flow (control group). The primary endpoint was survival at 2 years free from disabling stroke or device removal for malfunction or failure. The primary endpoint was achieved in 165 patients in the study group and 85 patients in the control group. They found that in respect to the primary endpoint, a small, intrapericardial, centrifugal-flow LVAD was found to be noninferior to an axial-flow LVAD (Rogers et al., 2017).

HeartMate 3 (Thoratec, Corp.)

Hanafy et al (2025) conducted a systematic review and meta-analysis attempting to aid in the clinical decision making of replacing older VAD models to the newest model the HeartMate 3(HM3). Researchers evaluated outcomes of different ventricular assist device (VAD) exchange strategies using studies published through February 25, 2023. A total of 49 studies involving 31,105 patients were included. Across all evaluated outcomes-including mortality, cerebrovascular accidents, other neurologic events, pump thrombosis, bleeding, and hospital admissions-HM3 consistently ranked as the best-performing device, demonstrating the lowest risk of adverse events and fewer hospital admissions compared with HeartMate 2 (HM2). Additionally, when complications occurred, exchanging HM2 or HeartWare ventricular assist devices for HM3 was associated with lower mortality than exchanging to the same device type, supporting HM3 as the preferred option, only recommended if there is a complication present.

Mehra et al (2022) conducted a 5-year observational study of the MOMENTUM 3 randomized trial reporting the composite end point of survival to transplant, recover, or LVAD support free of debilitating stroke or reoperation to replace the pump at 2 years. A total of 477 patients of 536 patients were still receiving LVAD support at 2 years contributed to the extended phase analysis. The 5-year estimate of survival to transplant (Kaplan-Meir estimate), recovery or LVAD support free of debilitating stroke or reoperation to replace the pump in the HeartMate 3 vs HeartMate II group was 54% vs 29.7%. The overall Kaplan-Meir survival was 58.4% in HeartMate 3 vs 43.7% in the HeartMate II group. Serious adverse outcomes of stroke, bleeding, and pump thrombosis were less

frequent in the HeartMate 3 group. Overall, the HeartMate 3 has a higher survival rate at 5 years and better composite outcome.

Inclusion criteria for MOMENTUM 3 trial included:

- Greater than or equal to 18 years with a BSA greater or equal to 1.2 m^2.
- 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 subjects must also meet one of the following:
    - On optimal medical management for at least 45 of the last 60 days and failing to respond
    - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.

Mehra et al (2016) conducted a comparison study looking at the original MOMENTUM 3 randomized clinical trial compared HeartMate 3 centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients with advanced heart failure that is refractory to standard medical therapy. There were 294 participants and out of those patients 152 were assigned to HeartMate 3 and 142 to the HeartMate II group. The primary end point was a composite of survival at two years free of disabling stroke or reoperation to replace a malfunctioning device at six months after implantation. Primary end point was met in 131 patients (86.2%) in patients with HeartMate 3 and in 109 (76.8%) in the HeartMate II patients. There were no significant differences between groups in the rates of death or disabling stroke. Reoperation for pump malfunction was more frequent in HeartMate 3. While there was no suspected or confirmed pump thrombosis in the HeartMate 3 patients, there were 14 patients (10.1%) in the HeartMate II group. Overall, HeartMate 3 had better outcomes over a 6-month period.

<u>MicroMed HeartAssist 5 (formally the DeBakey VAD Child)</u>

Publications have reported positive outcomes for children using VADs as a bridge to transplantation. Davies et al (2008) reported on the use of VADs in pediatric patients undergoing heart transplantation. Their analysis concluded that pediatric patients requiring a pre-transplantation VAD have similar long-term survival to those not receiving mechanical circulatory support. In 2014, a prospective randomized clinical trial was prepared to enroll participants, and in 2018 the trial was terminated for the inability to timely enroll.

<u>Berlin Heart EXCOR Pediatric VAD</u>

The Berlin Heart investigational device exemption (IDE) trial was a prospective, multicenter, single-arm, clinical cohort study of children 0 to 16 years with severe heart failure due to biventricular heart disease and actively listed for heart transplant. The primary endpoint was survival to heart transplantation or recovery (Almond et al., 2011). Fraser et al (2012) conducted a prospective, single-group trial of a VAD device designed specifically for children (16 years or younger) as a bridge to transplantation. The two cohorts were based on body surface area, with 24 patients in each group. Survival in the two cohorts receiving mechanical support was compared with survival in two

propensity-score-matched historical control groups on extracorporeal membrane oxygenation (ECMO). For participants in cohort 1 (with a body surface area of less than 0.7 m2), the median survival time had not been reached by 174 days, but in the matched ECMO group the median survival was 13 days. Cohort 2 (with a body surface area of 0.7 to less than 1.5 m^2) and the matched ECMO group, median survival rate was 144 days and 10 days, respectively. Adverse effects such as bleeding, infection, and strokes were found in both cohorts at very similar rates. This study showed that overall survival rates were higher with the VAD.

Impella 2.5 Cardiac Assist Device (AbioMed, Inc.)

Tariq et al (2024) conducted a systematic meta-analysis to evaluate the safety and efficacy of Impella in the treatment of acute myocardial infarction (AMI) that is associated with cardiogenic shock (CS). A total of 442 patients from 4 randomized control trials were included in this study. The inclusion criteria comprised of patients with CS as a complication of AMI receiving Impella or MCS device. The primary outcome includes 6 months all-cause mortality. Secondary end points are 30-day mortality, sepsis, limb ischemia, major bleeding events, and LVEF at follow-up. With the small sample size taken into consideration, the study did reveal that Impella significantly reduces 6-month all-cause mortality in patients with CA following an AMI compared to standard of care. However, they did see an increase in the odds of major bleeding events, limb ischemia, and sepsis risks associated with Impella. They do suggest that larger scale randomized control trials should be done to validate and assist with refining clinical guidelines.

O'Neil et al (2012) reported the results of the PROTECT II trial, it is a prospective, randomized clinical trial that identified and characterized a population of high-risk patients undergoing nonemergent PCI. In these patients, PCI resulted in a marked reduction of symptoms and increased left ventricular function. Hemodynamic support with Impella 2.5 did not result in a superior outcome of the primary end point at 30 days but showed a strong trend to superior outcome at 90 days in the total cohort and a significant improvement in the prespecified per protocol analysis at 90 days. Important adverse events continued to occur after 30-day follow-up, suggesting that intense medical observation is required for at least 90 days in these patients. The trial was terminated prematurely because of the data safety monitoring board's determination of futility. (O'Neill et al., 2012).

Dixon et al (2009) reported the results of the PROTECT I trial, it evaluated the effectiveness of the Impella 2.5 (n = 20) in patients undergoing high-risk percutaneous coronary intervention (PCI) at seven centers. Eligible patients had a left ventricular ejection fraction (LVEF) of less than 35%. The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 ± 0.6 h (range: 0.4 to 2.5 h). Mean pump flow during PCI was 2.2 ± 0.3 l/min. At 30 days, the incidence of major adverse cardiac events was 20% (two patients had a periprocedural myocardial infarction; two patients died at days 12 and 14). There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia. Two patients (10%) developed mild, transient hemolysis without clinical sequelae. None of the patients developed hemodynamic compromise during PCI. Other studies investigating the Impella device, although limited by small sample populations, have demonstrated its efficacy in providing circulatory support during high-risk percutaneous revascularization procedures and in post-cardiotomy patients.

Artificial Hearts

Several published clinical trials concluded that the SynCardia t-TAH is relatively safe and effective as a "bridge to transplant" in carefully selected heart transplant candidates.

Torregrossa et al (2014) conducted a retrospective study on patients as of December 2011. Included were 47 patients who received the TAH from 10 centers worldwide, the primary diagnosis was dilated cardiomyopathy in 23 patients, ischemic in 15 and "other" in 9. The data that was collected was on survival, infections, thromboembolic and hemorrhagic events, failure of device and antithrombotic therapy. The mean support time was 554 days. After a minimum of 1 year support, 72% of patients were successfully transplanted, 24% died while on device support, and 2% was still receiving support. Device failure was reported in 10% of patients. Major complications include infections 53%, driveline infections 27%, thromboembolic events 19%, and hemorrhagic events 14%. Overall SynCardia was proven to be reliable and effective in replacing the entire heart. It was noted that for patients that reached 1 year, device failure is acceptable and were likely to survive to transplantation, regardless of the infection and hemorrhagic events.

PROFESSIONAL GUIDELINE(S)

The 2023 ISHLT/HFSA issued guidelines for acute mechanical circulatory support. They stated that "Acute MCS should be initiated as soon as possible in patients with cardiogenic shock who fail to stabilize or continue to deteriorate despite initial interventions" (COR I, LOE B).

The 2022 American Heart Association, ACC, and HFSA Clinical Practice Guidelines for the Management of Heart Failure (Heidenreich, 2022) does not specifically address TAH but does state that in select patients with refractory HF, durable MCS is appropriate.

The 2020 American Association for Thoracic Surgery (AATS) and International Society for Heart and Lung Transplantation (ISHLT) guidelines (Kirklin 2020) discusses selected topics pertaining to mechanical circulatory support. The recommendations include preoperative evaluation and optimization and the use of PVADs in cardiogenic shock:

Techniques in cardiogenic shock (including, but limited to):

- "Percutaneous right ventricular assist device support should be considered for cardiogenic shock from primary right ventricular failure" (Class of recommendations (COR) IIa, Level of evidence (LOE) B).
- "Percutaneous LV to aorta pumps of appropriate size should be considered for cardiogenic shock from primary LV failure" (COR IIa, LOE B).
- "IABP support is recommended for cardiogenic shock complicating acute myocardial infarction, but additional mechanical support may be needed if prompt hemodynamic improvement is not forthcoming" (COR IIa, LOE A).
- "The possibility of biventricular support should be included in the surgical plan if biventricular failure is documented with CI < 2.0 L/min/m2, right atrial pressure >17 mm Hg, and CVP/ PCWP ratio >0.63" (COR IIa, LOE C).

- "Patients who undergo placement of temporary MCS (percutaneous VAD or ECMO) should have right ventricle function evaluated at regular intervals; if it remains poor and patient is a transplant candidate, consideration for biventricular support or TAH is advisable" (COR IIa, LOE C).
- "Patients who received an LVAD as bridge to transplant and remain with poorly controlled right ventricular failure (with or without a temporary right VAD) should be considered for longer term biventricular support or TAH before end-organ dysfunction ensues" (COR IIa, LOE C).
- "The use of biventricular support should be considered for patients who remain in refractory biventricular failure or experience persistent destabilizing ventricular dysrhythmias and have sufficient cavity size for the inflow cannulas. TAH can also be considered in these populations and in patients with infiltrative-restrictive cardiomyopathies, heart graft failure, thrombosed ventricles, and some cardiac tumors" (COR IIa, LOE C).

The 2015 Society for Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology Foundation (ACCF), Heart Failure Society of America (HFSA) and the Society for Thoracic Surgery (STS) Clinical Expert Consensus Statement on the use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care have the following recommendations:

Indications for percutaneous mechanical circulatory support (MCS):

- Complications of acute myocardial infarction (AMI);
- Severe heart failure in the setting of nonischemic cardiomyopathy;
- Acute cardiac allograft failure;
- Patients slow to wean from cardiopulmonary bypass following heart surgery;
- Refractory arrythmias;
- Prophylactic use for highly risk percutaneous coronary intervention (PCI);
- High-risk or complex ablation of ventricular tachycardia;
- High-risk percutaneous valve interventions.

For patients needing a high-risk PCI (patient with left main, last remaining conduit, or severe multivessel disease) and with severe left ventricular dysfunction (EF less than 35%) or recent decompensated heart failure; they recommend Impella or TandamHeart for anticipated technically challenging or prolonged PCI. For noncomplex PCI Impella should be used as a back up to IABP.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates cardiac devices as medical devices. All cardiac devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 19]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most

serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Jan 19]

Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	Indication
DeBakey VAD Child	MicroMed	Feb 2004	HDE H030003	Bridge to transplant in children 5-16 years old.
CentriMag	Thoratec (Abbott)	Dec 2019	PMA P170033	Post cardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	PMA P160035	Bridge to transplant or recovery
HeartMate 3	Thoratec (Abbott)	Aug 2017 Oct 2018	PMA P160054 PMA P160054/S 008	Bridge to transplant and destination

Available Percutaneous Ventricular Devices

Device	Manufacturer	Approval Date	FDA Clearance	Indication
TandemHeart	Cardiac Assist (LivaNova)	Sep 2011	510(k) K110493	Temporary Left ventricular bypass of Less than or equal to six (6) hours
Impella CP	Abiomed	Nov 2016	PMA P140003	Temporary (of Less than or equal to 6 hours) ventricular support devices indicated for the use during high-risk PCI Temporary Left ventricular support for less than or equal to four (4) days in cardiogenic shock
Impella 5.5	Abiomed	Nov 2016	PMA	Temporary Left ventricular support for less than or equal to 14 days in

Device	Manufacturer	Approval Date	FDA Clearance	Indication
			P140003	cardiogenic shock

Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	Indication
SynCardia Temporary Total Artificial Heart	SynCardia Systems	2002	510(k) P030011	Bridge to transplant in cardiac-eligible candidates at risk of imminent death from biventricular failure.

HDE: humanitarian device exemption; PMA: premarket approval

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
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
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Biventricular
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle

Code	Description
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	With cardiopulmonary bypass
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, arterial access only
33991	Both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous ventricular assist device, atrial or atrial venous cannula(s), 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
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report

HCPCS Codes

Code	Description
L8698	Miscellaneous component, supply, or accessory for use with total artificial heart system
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0480-Q0509	VAD components (code range)

ICD10 Codes

Code	Description
A18.84	Tuberculosis of heart
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure

Code	Description
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I21.01-I22.9	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (code range)
I40.0-I41	Acute myocarditis and myocarditis in diseases classified elsewhere (code range)
I50.1-I50.9	Heart failure (code range)
R57.0	Cardiogenic shock
Z76.82	Awaiting organ transplant status

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Total Artificial Heart

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Ventricular Assist Devices

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Artificial Heart Devices are not addressed in National or Regional Medicare coverage determinations or policies.

Ventricular Assist Devices (NCD 20.9.1) [accessed 2026 Jan 21]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

03/20/25, 03/19/26

Date	Summary of Changes
03/19/26	• Annual review, policy intent unchanged.
03/20/25	• New Policy created with content merged from CMP 7.01.65 and 7.01.07. Policy statement revised for percutaneous VADs to change from investigational to medically necessary.
03/20/25	• Original effective date