MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Ventricular Assist Devices**
Policy Number	**7.01.07**
Category	**Technology Assessment**
Original Effective Date	**12/02/99**
Committee Approval Date	**10/18/01, 09/19/02, 09/16/04, 07/21/05, 07/20/06, 05/17/07, 05/14/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 06/20/13, 05/22/14, 06/18/15, 06/16/16, 06/15/17, 06/21/18, 08/14/19, 08/15/19, 7/16/20, 07/15/21, 04/21/22, 03/23/23**
Current Effective Date	**03/23/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, ventricular assist devices (VAD) approved for use by the U.S. Food and Drug Administration (FDA) have been medically proven to be effective and, therefore, are considered **medically appropriate** for the following indications:

I. As a **bridge to transplantation** for patients who are diagnosed with severe ventricular heart failure and who:
   A. are approved as a heart transplant candidate by an approved heart transplant center; and
   B. have an imminent risk of dying before donor heart procurement; and
   C. are on optimal inotropic (influencing the contractility of muscular tissue) support; and
   D. are on an intra-aortic balloon pump (IABP), unless contraindicated.

II. As a **bridge to recovery** for post-cardiotomy patients who are unable to be weaned from cardiopulmonary bypass, or who have potentially reversible left ventricular dysfunction due to acute cardiogenic shock or acute myocarditis.

III. As **destination therapy** for adult patients who have end-stage heart failure, who meet the following criteria:
   A. Have been determined to be ineligible for heart transplantation (e.g., smoking); **AND**
   B. New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV **AND**
   C. Left ventricular ejection fraction ≤ 25% **AND**
   D. Inotrope-dependent; OR cardiac index <2.2 liters/min/m^2, while not on inotropes and also meeting one of the following:
      1. 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**

2. Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for at least 7 days. **AND**

E. 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*). **AND**

F. are of appropriate body size to support the LVAD implantation.

IV. Percutaneous ventricular assist devices are considered **investigational** for all indications.

Refer to Corporate Medical Policy #7.01.65 Artificial Hearts.

POLICY GUIDELINES

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. Contraindications for bridge to transplant:
   A. The patient has a condition that would generally exclude patients from heart transplant:
      1. Chronic irreversible hepatic, renal, or respiratory failure; or
      2. Systemic infection; or
      3. Blood dyscrasia.
   B. The patient has an uncorrected heart valvular disease, due to the potential problems with adequate function of the ventricular assist device.

III. 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.

IV. The DeBakey VAD Child (HeartAssist 5 pediatric VAD) has Humanitarian Device Exemption authorization from the FDA for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (ages five 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. The Berlin Heart EXCOR VAD has also received FDA approval through the Humanitarian Device Exemption (HDE) process. It is indicated for children with severe, isolated left ventricular or biventricular dysfunction, who are candidates for cardiac transplant, and who require circulatory support.

V. In the MOMENTUM 3 trial, the centrifugal-flow Heart- Mate 3 left ventricular assist device was associated with a less frequent need for pump replacement than the axial-flow HeartMate II left ventricular assist device and was superior to the axial-flow pump with respect to survival free of disabling stroke or reoperation to replace or remove a malfunctioning device.

DESCRIPTION

Ventricular assist devices (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).

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 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. Left ventricular assist devices (LVADs) are also used temporarily for post-cardiotomy patients who cannot be weaned from cardiopulmonary bypass immediately following surgery. VADs have also been investigated as a bridge to recovery in patients with potentially reversible left ventricular dysfunction due to acute cardiogenic shock or acute myocarditis.

RATIONALE

VADs can provide an effective bridge to transplantation, allowing patients to survive until a donor heart is available. Published studies report that use of a VAD does not compromise the success of subsequent heart transplantation and may actually improve post-transplant survival.

The use of VADs as destination therapy is supported by the REMATCH study, a randomized controlled trial that compared LVAD device transplantation with optimal medical management in 129 patients with end-stage heart failure who were not candidates for cardiac transplantation. The trial showed that patients who received a VAD had a longer survival rate than those treated with optimal medical therapy. Median survival was increased by approximately 8.5 months. Although adverse events were more likely in the VAD group, these appeared to be outweighed by better outcomes on function; NYHA class was significantly improved, as was quality of life among those living to 12 months. Two years of additional observation on REMATCH patients (Park, 2005) substantiated the continuing survival benefit of LVAD support. LVAD treatment more than doubled the survival seen at two years over optimal medical management.

VADs have been used as bridge to recovery 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.

A variety of devices have received approval for marketing by the FDA, encompassing both biventricular and left ventricular devices. The type of device used is dependent upon specific FDA-labeled indications. These devices include, but are not limited to:

I. HeartMate Sutures Not Applied Vented Electric Left Ventricular Assist System (SNAP VE LVAS) (Thoratec Corp.);
II. HeartMate II LVAD (Thoratec Corp.);
III. HeartMate 3 Left Ventricular Assist System (Thoratec Corp.);
IV. Impella 2.5/ Impella 5.0 (AbioMed Cardiovascular, Inc);
V. Abiomed BVS 5000 Biventricular Support System (AbioMed Cardiovascular, Inc.).

Two pulsatile devices, the HeartMate SNAP VE LVAS and the HeartMate XVE LVAS, have received FDA approval as destination therapy. The Heartmate II LVAD, a continuous flow device, received FDA approval as destination therapy on January 20, 2010. The premarket approval included two-year data from a study cohort of 200 patients randomly assigned 2:1 to either a HeartMate XVE or a HeartMate II. Patients implanted with the HeartMate II device had statistically significant improved two-year survival versus those patients implanted with the HeartMate XVE, in addition to improved quality of life. Forty-six percent of the 134 patients implanted with the HeartMate II were still living after two years, with no disabling stroke or need for reoperation, device replacement or repair, compared with 11% in the 66 patient control group. Approval was contingent on a post-approval follow-up study involving 247 patients for either two years or until outcome by Thoratec. On September 27, 2017, the FDA approved the HeartWare HVAD System (Medtronic, Inc.) for destination therapy in patients with advanced heart failure who are not candidates for heart transplant based on results from the ENDURANCE and ENDURANCE Supplemental trials. The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy. On December 18, 2020, Medtronic issued an Urgent Medical Device Communication informing physicians of an issue where the HVAD pump may experience a delay to restart or a failure to restart. The communication explained that a subset of HVAD devices included an internal pump component from three (3) specific lots that increased the risk of restart failure. Medtronic has not been able to pinpoint a root cause for each pump restart failure. On June 3, 2021, the FDA sent out another Urgent Medical Device Communication, notifying physicians to immediately stop new implants of the Medtronic HeartWare HVAD System and that prophylactic explant of the HVAD System was not recommended at this time.

In February 2004, the FDA approved a Humanitarian Device Exemption for the DeBakey VAD Child, a ventricular assist device for home and hospital use, for children ages five to 16 years who are awaiting a heart transplant. The FDA approved the exemption after reviewing data showing that the device had a reasonable probability of being safe and effective in children. Publications have reported positive outcomes for children using VADs as a bridge to transplantation. Using the UNOS database, 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**.** On December 16, 2011, upon successful completion of the so-called Berlin Heart investigational device exemption (IDE) trial, the FDA granted Humanitarian Device Exemption approval of the Berlin Heart EXCOR Pediatric VAD. The EXCOR has become the first pediatric-specific VAD that has gained widespread acceptance in North America. This is truly a landmark event for children suffering from terminal heart failure. The Berlin EXCOR Pediatric VAD is the only VAD which can be used for newborns, infants and small children ≤ 25 kg.

Prior to April 2008, only pulsatile LVAD devices were FDA-approved for long-term use. Non-pulsatile axial flow devices are smaller in size and have other technical advantages over pulsatile models. The HeartMate II (Thoratec) was the first continuous flow device to receive FDA approval as a bridge to transplant for treatment of advanced-stage heart failure. The approval was based on one-year follow-up data from the first 194 HeartMate II bridge-to-transplant patients enrolled in the trial. Results included in the final PMA submission were:

I. The median duration of support was 132 days, and the cumulative patient support in the trial was 109 years.
II. Survival to cardiac transplantation, recovery or ongoing on HeartMate II support, was 80% at six months and 77% at one year.
III. 84% of the patients survived to hospital discharge or transplantation.
IV. Significant improvements were observed across all measures of functional status and quality of life, as compared to baseline status.
V. The incidence of major adverse events with comparable definitions, including infections, strokes, and bleeding requiring surgery, was significantly lower than what was clinically observed in the previous bridge-to-transplant study of the HeartMate VE LVAS.

The HeartMate 3 Left Ventricular Assist System (Thoratec) was approved by the FDA on August 23, 2017. Per the manufacturer’s website, the HeartMate 3 system can pump up to 10 liters of blood per minute and 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. The magnets keep the rotor in place by calibrating tens of thousands of times per second, to ensure that it stays suspended and centered within the pump, no matter the speed settings used by a physician. This ensures that the pump is performing effectively while continuing to deliver the best patient therapy possible. The HeartMate 3 system also uses the industry's widest pump pathway, designed so the blood cells are not damaged when passing through. The system also relies on a built-in "pulse" programmed to help ensure the blood continues to move through without becoming static, thereby reducing the risk of blood clot formation. The HeartMate 3 blood pump should not be used in patients who cannot tolerate, or who are allergic to, anticoagulation therapy (blood thinners), because these medicines are required to prevent blood clots from forming in the pump.

The MOMENTUM 3 trial compared HeartMate 3 centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as a bridge to transplant or destination therapy; inclusion criteria included

1. NYHA Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV;
2. Left ventricular ejection fraction ≤ 25%;
3. Inotrope-dependent OR cardiac index <2.2 liters/min/m^2 while not on inotropes and subjects must also meet the following: On optimal medical management for at least 45 of the last 60 days and failing to respond or with advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.

HeartMate 3 received PMA approval as a bridge to transplant therapy in August 2017 and as destination therapy in October 2018. The destination therapy indication was based on 2-year results from MOMENTUM 3, which showed superiority of the HeartMate 3 device compared to HeartMate II on the composite primary outcome, survival at 2 years free of disabling stroke or reoperation to replace a malfunctioning device (RR, 0.84; 95% CI, 0.78 to 0.91, p<.001)(Mehra et al., 2019). Prevalence of stroke at 2 years was lower in the HeartMate 3 than the HeartMate 2 group (10.1% vs 19.2%; p=.02) (Columbo et al.,2019). Measures of functional capacity and Health-Related quality of life did not differ between the 2 devices at 6 months (Cowger et al., 2018).

The Jarvik 2000, a non-pulsatile axial flow blood pump, is in phase II and III clinical trials. The Jarvik 2000 is used by hospitals in the United States as a bridge to heart transplant under an FDA-approved clinical investigation. In Europe, the Jarvik 2000 has earned CE Mark certification for both bridge-to-transplant and lifetime use. As an investigational device, the Jarvik 2000 has been implanted in more than 200 patients dying of heart failure.

AbioMed, Inc announced the FDA Section 510(k) clearance for its Impella 2.5 cardiac assist device on June 2, 2008. The Impella 2.5 is inserted percutaneously via the femoral artery into the left ventricle, to provide 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. The PROTECT I trial (Dixon, *et al*. 2009) 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.

On August 18, 2021 the FDA granted breakthrough device designation to Abiomed's Impella expandable percutaneous heart pump (ECP). The designation means the FDA will prioritize Impella ECP's regulatory review processes including design iterations, clinical study protocols and pre-market approval (PMA) application. Impella ECP is the smallest heart pump in the world and the first to be compatible with small bore access and closure techniques. It measures 9 French (3 millimeters) in diameter upon insertion and removal from the body. While in the heart, it expands to support the heart's pumping function, providing flow greater than 3.5 L/min. This device is considered only for investigational use.

The Society for Heart and Lung Transplantation (Gronda, 2006) published guidelines for the care of cardiac transplant candidates that included considerations for the use of ventricular assist devices. The recommendations for VAD therapy are based on a comparison of short and long-term survival and QOL outcomes with conventional therapy.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

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

Code	Description
33980	Removal 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 (**E/I**)	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, arterial access only
33991 (**E/I**)	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33992 (**E/I**)	Removal of percutaneous ventricular assist device, atrial or atrial venous cannula(s), at separate and distinct session from insertion
33995 **(E/I)**	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997 (**E/I**)	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
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
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

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*Key Article

KEY WORDS

Bridge to heart transplant, Assist Devices, ventricular, LVAD, VAD, Destination Therapy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). Please refer to the following NCD website for Medicare members:
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=360&ncdver=2&keyword=ventricular%20assist&keywordType=starts&areaId=all&docType=NCD&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&