

MEDICAL POLICY

SUBJECT: VENTRICULAR ASSIST DEVICES	EFFECTIVE DATE: 10/18/01 REVISED 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
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare 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.</i>	

POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, FDA approved ventricular assist devices have been medically proven to be effective and therefore, **medically appropriate** for the following indications:

- I. When used as a bridge to transplantation for patients diagnosed with severe ventricular heart failure who meet all of the following criteria:
 - A. Approved as heart transplant candidate by an approved heart transplant center;
 - B. An imminent risk of dying before donor heart procurement;
 - C. On optimal inotropic (influencing the contractility of muscular tissue) support; and,
 - D. 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 for patients with potentially reversible left ventricular dysfunction due to acute cardiogenic shock or acute myocarditis.
- III. As destination therapy for patients with chronic end-stage cardiac failure who meet all of the following criteria based on the REMATCH study:
 - A. Evaluated as a heart transplant candidate by an approved heart transplant center; but determined to be ineligible for heart transplantation. AND
 - B. NYHA class III or IV heart failure for at least 28 days who have received at least 14 days support with an intraaortic balloon pump or are dependent on IV inotropic agents OR class IV end-stage heart failure that has failed to respond to optimal medical management for at least 60 of the last 90 days, AND
 - C. Functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min; AND
 - D. 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 regarding Artificial Hearts.

POLICY GUIDELINES:

- I. The following guidelines may be used as hemodynamic selection criterion for bridge to transplant:
 - A. Either a left atrial pressure of 20m Hg or a cardiac index of less than 2.0L/min/m;
 - B. Patients are generally being treated as inpatients and categorized by the American Heart Association, or comparable, as Class IV CHF; and
 - C. Classified as Status I by the United Network for Organ Sharing (considered the highest priority for transplantation).
- II. Contraindications for bridge to transplant:
 - A. Includes conditions which would generally exclude patients for heart transplant:
 1. Chronic irreversible hepatic, renal, or respiratory failure, or
 2. Systemic infection, or
 3. Blood dyscrasia.
 - B. Uncorrected valvular diseases, due to the potential problems with adequate function of the ventricular assist

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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 for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA greater than or equal 0.7 m² and less than 1.5 m²) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation. 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 and has also received FDA approval through the humanitarian device exemption (HDE) process.

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 cardiectomy 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), 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-cardiectomy 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) substantiates the continuing survival benefit of LVAD support. LVAD treatment more than doubled the survival seen at 2 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 cardiectomy 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 from the U.S. Food and Drug Administration (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)

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- (Thoratec Corp.);
- II. HeartMate® II LVAD (Thoratec Corp.);
- III. HeartMate 3™ Left Ventricular Assist System (Thoratec Corp.);
- IV. Impella 2.5®/ 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 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 vs. those 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.

In February 2004, the FDA approved a Humanitarian Device Exemption (HDE) for the DeBakey VAD® Child, a ventricular assist device for home and hospital use, for children aged 5 to 16 awaiting a heart transplant. The FDA approved the HDE for the VAD after reviewing data that showed 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 use of VADs in pediatric patients undergoing heart transplantation. Their analysis concluded that pediatric patients requiring a pretransplantation VAD have similar long-term survival to those not receiving mechanical circulatory support.

Prior to April 2008, only pulsatile LVADS 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) is the first continuous flow device to receive FDA approval as a bridge to transplant (BTT) for treatment of advanced-stage heart failure. The approval was based on one-year follow-up data from the first 194 HeartMate II BTT 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 BTT 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 it stays suspended and centered within the pump, no matter the speed settings used by a physician. This ensures 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, therefore reducing the risk of blood clot formation. The HeartMate 3 blood pump should not be used in patients who cannot tolerate, or who are

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allergic to, anticoagulation therapy (blood thinners) because these medicines are required to prevent blood clots from forming in the pump.

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 510(k) clearance for its Impella 2.5 cardiac assist device 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 liter of blood per minute is 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 PCI at seven centers. Eligible patients had a LEF of less than 35%. The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 ± 0.6h (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% (2 patients had a periprocedural myocardial infarction; 2 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.

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 and are available at: [http://www.jhltonline.org/article/S1053-2498\(06\)00251-8/pdf](http://www.jhltonline.org/article/S1053-2498(06)00251-8/pdf).

CODES: Number Description

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.

<u>CPT:</u>	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
	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

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- 33990 (E/I) Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
- 33991 (E/I) Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
- 33992 (E/I) Removal of percutaneous ventricular assist device at separate and distinct session from insertion
- 93750 Interrogation of ventricular assist device (VAD), in person, with physician 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

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HCPCS: Q0477 Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only (*effective 1/1/2018*)

Q0480-Q0509 VAD components (code range)

- ICD10:**
- 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 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 Artificial Hearts and Related Devices. Please refer to the following NCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=6&bc=AgAAgAAAAAAAAAA%3d%3d&>.