I. POLICY

It is the policy of MedStar Health, Inc. to cover Ventricular Assist Devices when they are medically necessary (refer to CRM.015.MH Medical Necessity policy) and covered under the member’s specific benefit plan.

MedStar Health, Inc. recognizes Ventricular Assist Devices as appropriate and consistent with good medical practice when performed according to the clinical criteria described in this policy. Coverage will be considered after review on an individual basis for the specific indications detailed in this policy.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

American College of Cardiology Foundation/ American Heart Association (ACCF/AHA) Stages of Heart Failure (HF) - (stages of HF that recognize both risk factors and abnormalities of cardiac structure are associated with HF):

Stage A- At high risk for HF but without structural heart disease or symptoms of HF.
Stage B- Structural heart disease but without signs or symptoms of HF.
Stage C - Structural health disease with prior or current symptoms of HF exhibited.
Stage D - Refractory HF exhibited which requires special interventions.

**New York Heart Association (NYHA) Functional Classification of Heart Failure** (heart failure classification system based on severity of symptoms with everyday activities):

- **Class I** (None) – Members with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.

- **Class II** (Mild) – Members with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity (moderate exertion) results in fatigue, palpitation, dyspnea, or anginal pain.

- **Class III** (Moderate) – Members with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain.

- **Class IV** (Severe) – Members with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

### III. PURPOSE

The purpose of this policy is to provide the prior-authorization criteria for coverage of Ventricular Assist Devices.

### IV. SCOPE

This policy applies to various MedStar Health, Inc departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.
V. PROCEDURE

A. Medical Description / Background

A Ventricular Assist Device (VAD) or Mechanical Circulatory Support (MCS) is a mechanical device that is surgically or percutaneously implanted to one or both ventricles of the heart to assist or completely replace the pumping function of a weakened/damaged heart. A VAD differs from an artificial heart in that it does not completely take over cardiac function nor does it require removal of the patient’s heart.

VADs are designed to assist either the left ventricle (LVAD), the right ventricle (RVAD), or both sides simultaneously (BiVAD). The pump itself is typically implanted in the patient’s body although some are placed outside of the body with blood delivered to and pumped from the device through percutaneous cannula. VADs can be temporary or permanent. Temporary VADs are implanted surgically or percutaneously; whereas, Temporary VADs are implanted surgically.

The two types of pumps used in VADs are:

- Pulsatile – (prior generation) the pulsatile type pump fills with blood and when the sensors indicate it is full, the blood is ejected out of the device through a one way valve to the aorta or pulmonary artery mimicking the action of a beating heart.
- Continuous-flow (current generation) – these pumps have only one moving part, the impeller, which continuously pulls blood from the ventricle, rather than having a chamber that sequentially empties and fills.

A total artificial heart (TAH) in contrast to the VAD is an implantable biventricular support that serves as a total replacement for both ventricles of the heart.

Some circulatory assist devices are placed percutaneously and are referred to as percutaneous VADs. The intended duration of use is generally for periods appropriate to cardiopulmonary bypass- up to 6 hours. Examples of these include:

- The Impella Recover LP 2.5 percutaneous cardiac support system (U.S. Food and Drug Administration (FDA) approval 2008) is intended for short term circulatory support for conditions characterized by profoundly reduced ventricular function and provides 2.5 L/min forward flow from the left ventricle into the systemic circulation.
• The Impella CP (Cardiac Power) (FDA approval 2012) which provides 3.5L of flow and the Impella 5.0 LP (FDA approval 2009), which contains a larger pump, permits a flow range up to 5 liters per minute and is used for the same indications.

• Tandem Heart pVAD (FDA approval 2006) allows for percutaneous access through the femoral vein and uses a transseptal cannula that allows direct unloading of the left heart at blood flow rates sufficient to sustain patients. Unlike the intra-aortic balloon pump with a pump flow rate of 1.5 L/min, the TandemHeart can provide up to 4 L/min of support. This device can be used as a bridge to recovery or transplant.

• CentriMag Right Ventricular Assist System (RVAS) (HDE 2008) is an external device that can be used for temporary support for acute right heart failure.

Implantable devices are placed in a preperitoneal pocket or in the patient’s thoracic cavity. Most permanent VADs are LVADs. The LVAD receives blood from the left ventricle and delivers it to the proximal aorta just distal to the aortic valve. The RVAD receives blood from either the right atrium or ventricle and delivers it to the pulmonary artery just distal to the pulmonary valve. Sometimes a patient will require both ventricles to be supported by a separate device, known as biventricular assist devices (BiVADs).

Patients who receive a permanently implantable VAD are able to return to their activities of daily living and must carefully follow the guidelines provided by their health care team. A detailed education program is provided to the patient and their caregivers to ensure safe and proper use of the device and to trouble-shoot potential emergency situations. A patient can be supported on a VAD for years depending on the device used and the patient’s overall condition.

**Indications for use of VADs include:**

**I. Bridge-to-transplant therapy** is intended for patients with end-stage heart failure who are awaiting transplant, but who are declining despite optimal medical therapy. The VAD supports the patient until a suitable heart donor becomes available. The VAD resolves the heart failure state and allows the patient to rehabilitate while typically improving end-organ function due to the improved cardiac output. Patients are ultimately expected to be discharged home while waiting for transplant on MCS.

Examples of FDA approved bridge-to-transplant VADs include but are not limited to the following:

• HeartWare Ventricular Assist System (HVAD) (FDA approval 2012)
• Thoratec HeartMate II (FDA approval 2008)
II. Destination therapy is to support patients with end-stage heart failure who are not candidates for heart transplantation. Coverage for destination therapy is based on patient selection criteria including:

- New York Heart Association (NYHA) class;
- Time on optimal medical management;
- Left ventricular ejection fraction (LVEF) and
- Peak oxygen consumption.

An example of an FDA approved destination therapy VAD is the Thoratec HeartMate II.

III. Postcardiotomy is approved for short periods of reversible heart failure following recovery from open heart surgery for patients who were unable to be weaned from cardiopulmonary bypass.

Examples of postcardiotomy recovery VADs include but are not limited to the following:

- ABIOMED AB5000 (FDA approval 2003)
- Thoratec CentriMag (HDE 2008)

IV. Pediatric VADs

ECMO (extracorporeal membrane oxygenation) has been the mainstay of mechanical circulatory support for infants and children but is not suitable for long-term use. There are currently only two VAD’s approved for pediatric use.

- Berlin Heart’s EXCOR Pediatric VAD (air-driven pump) had been approved by the FDA (2007) for infants up to teenagers as an Investigational Device Exemption (IDE) for bridge-to-transplant and bridge-to-recovery. In 12/16/11, after review of IDE Clinical Trial results, this device was considered part of the FDA Humanitarian Device Exemption (HDE) program (H100004) for use as bridge-to-transplant for pediatric patients with severe isolated ventricular or biventricular dysfunction. The pumps in the device have been developed to have different stroke volumes that can be used for newborns, infants, and small children safely providing a lower risk of thromboembolic events when compared to VADs designed for adults.
• DeBakey VAD Child (now called the HeartAssist 5 VAD) also part of the FDA (2004) HDE program (H030003) is indicated for home/hospital use as a bridge-to-transplant for pediatric patients.

B. Specific Indications

Implantation of a VAD requires meeting both general criteria and specific criteria for each indication of use.

General criteria for VAD implantation include all of the following:
1. The VAD must be FDA-approved for that specific indication of use.
2. The procedure must be performed in a facility that is a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) and credentialed by the Joint Commission on Accreditation of Healthcare Organizations under the Disease Specific Certification Program for VADs.
3. The facility must have at least one member of the VAD team with experience implanting at least 10 VADs over the course of the previous 36 months.

Specific Criteria for each indication of use:

I. Bridge-to-Transplant (All of the following criteria must be met):
1. Device must be FDA-approved for bridge-to-transplant use and used according to labeling instructions.
2. Patient must be listed as a candidate for heart transplantation or undergoing evaluation based on a decision for patient’s candidacy by an interdisciplinary patient selection committee (including but not limited to medical doctors, nursing coordinators, social workers, nutritionists, etc.) at a Medicare approved heart transplant center. (See Section F-Variations for Medicare indication)
3. The implanting site, if different from the transplant center, must receive written permission from the Medicare approved heart transplant center under which the patient is listed prior to implantation of the VAD.
4. The Medicare approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable.

II. Destination Therapy (All of the following criteria must be met):
1. Device must be FDA-approved for destination therapy use and used according to labeling instructions.
2. Patient has been classified as New York Heart Association (NYHA) Class IV end-stage ventricular heart failure or ACCF/AHA Stage D heart failure and is not a candidate for a heart transplant.
3. Has a left ventricular ejection fraction (LVEF) < 25%.
4. Has failed to respond to optimal medical management (including beta blockers and angiotensin-converting-enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or IV inotrope dependent for 14 days.
5. Has demonstrated functional limitation with a peak oxygen consumption of ≤14 ml/kg/min unless balloon-pump or inotrope-dependent or physically unable to perform the test.

III. Postcardiotomy ventricular dysfunction (Both of the following criteria must be met):
1. Device is FDA-approved for this purpose and used according to labeling instructions.
2. All appropriate measures have been attempted to wean patient from the heart bypass such as pharmacologic agents, intra-aortic balloon pump (if applicable).

IV. Pediatric VADs (Either of the following criteria must be met):
A. Device is FDA approved for bridge-to-transplant and used according to labeling instructions.
B. Used in the context of Category B IDE /HDE clinical trial or as a routine cost in a clinical trial (refer to MP. 078. MH- Clinical Trials-Coverage of Routine Care Costs and/or MP.079. MH- Experimental and Investigational Services):
   - HeartAssist 5 VAD (MicroMed DeBakey VAD Child) – HDE device used for children ages 5 to 16 years with NYHA Class IV end-stage heart failure, who have been listed as a candidate for heart transplant, with Body Surface Area (BSA) ≥ 0.7 m² and < 1.5 m² and are refractory to medical therapy.
   - Berlin Heart EXCOR Pediatric VAD – HDE device used for infants up to teenagers (0 to 16 years) suffering from NYHA Class IV end-stage heart failure who are refractory to medical therapy and have been listed as a candidate for heart transplantation.

C. Limitations
A. Use of a non-FDA-approved device except in the context of Category B IDE exemption clinical trial or as a routine cost in a clinical trial (refer to
B. Patients, parents, or legal guardians who will be unable to follow the guidelines provided by their VAD health care team for use of the device.

C. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions.

D. Prior authorization is required unless the VAD is implanted emergently and then notification is still required after implantation so that Case Management may assist these patients.

E. Irreversible multiple organ dysfunction.

F. Active systemic infection.

G. Severely restricted pulmonary function.

H. Active malignancy (can be reviewed on a case-by-case basis when supported by documentation from an oncologist that expected survival with their cancer is at least 70% at 2 years).

I. Blood clotting disorders (can be reviewed on a case-by-case basis as this can be frequently present in patients with heart failure and patients who cannot be adequately anticoagulated).

J. Major neurological deficit.

D. Information Required for Review

In order to determine medical necessity for coverage of Ventricular Assist Devices, adequate information must be furnished by the treating physician. Necessary documentation includes but is not limited to the following items when applicable to the indication for use:

- Patient’s clinical history, diagnosis and treatment history.
- Name of ventricular assist device with a copy of the FDA approval with the scope of the indication that was approved.
- Documentation of approval /listing as a candidate for heart transplant or documentation of decision for heart transplant candidacy by interdisciplinary patient selection committee.
- If Clinical Trial or IDE/HDE refer to MP. 078. MH Clinical Trials and/or MP. 079. MH Experimental and Investigational Services for additional required information.

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).

2. If referred, the Medical Director determines if the requested service is
medically necessary and appropriate.

3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member’s benefit plan.

F. Variations

For the Medicare product –
- For criteria of Bridge-to-Transplant, Patient must be approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center.
- Requests for Clinical Trials and related costs for Medicare members should be submitted directly to Original Medicare and not to MedStar Health, Inc.

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable CPT coding:

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
</tr>
<tr>
<td>33979</td>
<td>Insertion of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33981</td>
<td>Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump</td>
</tr>
<tr>
<td>33982</td>
<td>Replacement of ventricular assist device pump(s);</td>
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implantable intracorporeal, single ventricle, without
cardiopulmonary bypass

33983  Replacement of ventricular assist device pump(s);
implantable intracorporeal, single ventricle, with
cardiopulmonary bypass

33991  Insertion of ventricular assist devices, percutaneous
including radiological supervision and interpretation; arterial
and venous access, with transseptal puncture

I. References

Medical Literature/Clinical Information:
   Society for Heart and Lung Transplantation Guidelines for mechanical
circulatory support: Executive summary. The Journal of Heart and Lung
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e240-e327.  https://circ.ahajournals.org/content/128/16/e240.extract
   for acute heart failure. Published: 1/4/2012.
   http://members2.ecri.org/Components/Target/Documents/Print/10429.pdf
4. ECRI Institute. Emerging Technology Report; Total artificial heart as
   bridge to transplantation and destination therapy. Published: 12/07/2012.
   http://members2.ecri.org/Components/Target/Pages/10451.aspx
   (CentriMag) as temporary support for severe heart failure. Published:
   6/29/2010
   https://members2.ecri.org/Components/Target/Pages/10160.aspx
6. ECRI Institute. Forecast; Smaller continuous –flow LVAD may benefit end-
   http://members2.ecri.org/Components/Forecast/Pages/11792.aspx
   2009 Dec; 88(6):1822-1827.  http://ac.els-
   cdn.com/S0003497509015860/1-e2.0-S0003497509015860-
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   00000aab0f02&acdnat=1371071096_42586ce7a36bb7686ca2d38c35f6a
   646
8. ECRI Institute. Health Technology Trend. Current state and outlook of pediatric VADs in the U.S. Published: 10/01/2008. [Link](http://members2.ecri.org/Components/Trends/Pages/11067.aspx)

**Regulatory/Government Source:**


Disclaimer:

MedStar Health Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health Inc. reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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