Ventricular Assist Devices

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Policy

Evolent Health considers **Ventricular Assist Devices (VADs)** medically necessary for the following indications:

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:

1. **Bridge-to-Transplant (All of the following criteria must be met)**:
   a) Device must be FDA-approved for bridge-to-transplant use and used according to labeling instructions.

   b) Member is approved and 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.)

   [See Variations for Medicare approved heart transplant center]

   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.

   The Medicare approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

2. **Destination Therapy (All of the following criteria must be met):**
   a) Device must be FDA-approved for destination therapy use and used according to labeling instructions.

b) Patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation, and meet all of the following conditions:
    1. Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
    2. Have a left ventricular ejection fraction (LVEF) < 25%, and,
    3. Have 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.

3. Postcardiotomy ventricular dysfunction (Both of the following criteria must be met):

a) Device is FDA-approved for this purpose and used according to labeling instructions.
b) All appropriate measures have been attempted to wean patient from the heart bypass such as pharmacologic agents, intra-aortic balloon pump (if applicable).

4. 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 PA-078- Clinical Trials-Coverage of Routine Care Costs and/or PA-079- 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.

Limitations

A. Use of a non-FDA-approved device except in the context of Category B IDE exemption clinical trial
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.

Background
A ventricular assist device (VAD) or left ventricular assist device (LVAD) is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood. Improvement in the performance of the native heart may allow the device to be removed.

A VAD differs from an artificial heart. An artificial heart is a biventricular replacement device which requires removal of a substantial part of the native heart, including both ventricles. Removal of this device is not compatible with life, unless the patient has a heart transplant.

Destination therapy is for patients that require permanent mechanical cardiac support.

Post-cardiotomy is the period following open-heart surgery.

Variation for the Medicare product –
For criteria of Bridge-to-Transplant, member is approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center and the implanting site, if different than the Medicare-approved 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.

Codes:

CPT Codes

Code	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33991	Insertion of ventricular assist devices, percutaneous including radiological supervision and interpretation; arterial and venous access, with transseptal puncture

References

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2. Centers for Medicare and Medicaid Services (CMS): National Coverage Determination (NCD) No. 20.9- Artificial hearts and related devices, Effective date November 9, 2010. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&NCAId=211&ver=20&NcaName=Artificial+Hearts&bc=ACAAAAAAIAAA&
3. Centers for Medicare and Medicaid Services (CMS): Medicare Learning Network (MLN) Matters MM7220- Ventricular assist devices (VADs) as destination therapy. Effective date: November 9, 2010. Updated September 18, 2014. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7220.pdf
4. Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: Executive summary. The Journal of Heart and Lung Transplantation. September 2013; 32: 157-187. https://www.ncbi.nlm.nih.gov/pubmed/23352391

5. Gregoric ID, Loyalka P, Radovancevic R, et al. Tandem Heart as a rescue therapy for patients with critical aortic valve stenosis. Ann Thorac Surg. 2009 Dec; 88(6):1822-1827. http://www.ncbi.nlm.nih.gov/pubmed/19932242
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10. U.S. Food and Drug Administration (FDA). Medical Devices. Device Approvals and Clearances. Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD) - H100004. Approval Date: Dec. 16, 2011. Page last updated: 12/4/2012. https://www.fda.gov/media/102643/download
11. Yancy CW, Jessup M, Bozkurt B, et al. 2013 American College of Cardiology Foundation/ American Heart Association (ACCF/AHA) Guideline for the Management of Heart Failure. Circulation. 2013: 128: e240-e327. https://circ.ahajournals.org/content/128/16/e240.extract

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