



Ventricular Assist Devices (VAD)

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Purpose:

To provide guidelines for ventricular assist devices (VAD) for the Medical Department staff for reference when making benefit determinations.

Compliance Status

- Centers for Medicare & Medicaid Services (CMS)

Definition

- Ventricular assist devices (VADs) are used to assist the left ventricle (LVADs), the right ventricle (RVADs), or both, and removal of the native heart is not necessary; VADs do not replace the heart, but rather work with the Member's own heart to pump sufficient blood throughout the body, and, thus, are used as auxiliary or parallel pumps. The VAD consists of a pump, a control system, and an energy supply. There has been the recent introduction of percutaneous left ventricular assist devices (pVADs) that provide active circulatory support requiring less residual left ventricular function.
- All VADs must be implanted in a facility approved by Medicare to perform the procedure.

Coverage Guidelines

Use of an FDA-approved *ventricular assist device (VAD)* is covered when used as labeled for the indications listed below:

1. As a bridge to transplantation for Members who meet ***all*** of the following criteria:
 - Is an approved heart transplant candidate;
 - Has irreversible, terminal heart disease;
 - Symptoms of advanced heart failure consistent with NYHA class IV limitations despite optimal medical management and requiring the initiation of inotrope therapy and/or intra-aortic balloon pump.
2. For short-term use in Members who present with cardiogenic shock with hemodynamic instability despite optimal medical management including the use of inotrope therapy and intra-aortic balloon pump when there is a likelihood of myocardial recovery.



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3. As destination therapy in Members meeting ***all*** of the following criteria:
 - New York Heart Association (NYHA) class IV end-stage left ventricular heart failure;
 - Documented ineligibility for human heart transplantation; and
 - Peak oxygen consumption less than or equal to 14ml/kg unless balloon pump- or inotrope-dependent or physically unable to perform the test; and
 - 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 seven (7) days, or IV inotrope-dependent for 14 days; and
 - Have a left ventricular ejection fraction (LVEF) < 25%.
4. In pediatric Members for use to provide temporary left sided mechanical circulatory support as a bridge to cardiac transplantation must meet all the following criteria:
 - NYHA Class IV end-stage heart failure refractory to medical therapy;
 - Is listed candidate for cardiac transplantation.

Use of an FDA-approved *percutaneous left ventricular assist device (pVAD)* is covered when used as labeled for the indications listed below:

1. Cardiogenic shock
2. Severe decompensated heart failure
3. Acute MI
4. Bridge to transplant
5. High risk PCI:
 - Unprotected left main or last patent conduit and EF less than or equal to 35% or
 - Three (3) vessel disease and EF less than or equal to 30%

Exclusion Criterion

- Use of a non-FDA approved ventricular assist device is considered investigational.



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References:

1. Aaronson KD, Eppinger MJ, Dyke DB, et al. Left ventricular assist device therapy improves utilization of donor hearts. *J Am Coll Cardiol.* 2002;39(8):1247-1254.
2. Aaronson KD, Patel H, Pagani FD. Patient selection for left ventricular assist device therapy. *Ann Thorac Surg.* 2003;75(6 suppl):S29-S35.
3. Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. NCD 100-3, Sec. 20.9 and LCDs.
4. Stevenson LW, Miller LW, Desvigne-Nickens P, et al. Left ventricular assist device as destination for patients undergoing intravenous inotropic therapy: a subset analysis from REMATCH (Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure). *Circulation.* 2004;110(8):975-981.
5. Food and Drug Administration (FDA) website. Ventricular Assist Device (VAD).
6. HAYES technology Assessment Report Ventricular Assist Devices.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.