

Ventricular Assist Device - VAD

Administrative Process

Requires prior approval.

Definitions

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart in pumping blood. These devices are used for support of blood circulation after open heart surgery, as a bridge to a heart transplant, or as destination therapy.

Coverage

Insertion of Ventricular Assist Devices (VADs) is covered when it meets the criteria listed below and is performed at a HealthPartners Designated Transplant Center. (See Designated Transplant Centers document for a list.)

Indications that are covered

1. Post-cardiotomy

Post-cardiotomy is the period following open-heart surgery. VADS used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

2. Bridge to Transplant

Bridge to transplant VADs are used while a patient is awaiting a heart transplant. VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. In addition, the member must be approved and listed as a candidate for heart transplantation at a HealthPartners Designated Transplant Center.

3. Destination Therapy

Destination therapy is for patients that require permanent mechanical cardiac support. VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose, and the device is used according to the FDA-approved labeling instructions. VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

- a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;
- b. The patient has left ventricular ejection fraction (LVEF) <25%;
- c. The patient has demonstrated functional limitation with a peak oxygen consumption of <12ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and
- d. The patient has the appropriate body size to support the VAD implantation.

Indications that are not covered

1. Artificial Heart

Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the entire human heart, the device is not covered for this use.

2. All other indications for the use of VADs not otherwise listed remain non covered.

Products

Consult your plan documents (Membership Contract, Summary Plan Description [SPD], Evidence of coverage [EOC] or similar plan document) to determine governing contractual provisions, including exclusions and limitations relating to your specific plan. These guidelines apply to most, but not all, plans offered by HealthPartners. We strive to ensure that the contents of this site are correct and complete, but to verify your benefits, please check your contract or SPD, or contact Member Services. In the event of a conflict between your specific plan documents and this general information, the plan documents will govern. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy contact Member Services at 952-883-7979 or 800-233-9645.

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These coverage criteria are adapted from the CMS National Coverage Decision 20.9 Artificial Hearts and Related Devices -

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.9&ncd_version=3&basket=ncd%3A20%2E9%3A3%3AArtificial+Hearts+and+Related+Devices