BlueCross BlueShield of North Carolina

Medicare Part C Medical Coverage Policy

Ventricular Assist Device (VAD)

Origination: November 23, 2004
Review Date: September 15, 2021
Next Review: September, 2023

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE

A ventricular assist device (VAD) or left ventricular assist device (LVAD) is used to assist a damaged or weakened heart to pump blood. The device is surgically attached to one or both intact ventricles and 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.

These devices are used for the support of blood circulation post-cardiotomy (the period following open heart surgery), as a bridge to heart transplant, or as a destination therapy.

POLICY STATEMENT

Coverage will be provided for a VAD when it is determined to be medically necessary based on the medical criteria and guidelines shown below are being met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

INDICATIONS FOR COVERAGE

Preauthorization by the Plan is required;

1. Post-cardiotomy is the period following open heart surgery. VADs are used for support of blood circulation in the period and are covered only if **used according to the Food and Drug Administration (FDA)- approved labeling instructions.**

2. Left Ventricular Assist Devices (LVADs) are covered if they are FDA approved for short-term *(e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:*
   A. The member has *New York Heart Association (NYHA) Class IV heart failure; and*
   B. a left ventricular ejection fraction (LVEF) ≤ 25%; and
   C. Are inotrope dependent OR
      have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
      i. Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond: **or**
      ii. Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

3. Category B investigational device exemption clinical trials or as a routine cost in a clinical trial defined under section 310.1 of the NCD. (In this case, refer to the Medical Policy on Clinical Trials).

WHEN COVERAGE WILL NOT BE APPROVED

All other indications for the use of VADs not listed above.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

Applicable codes: 33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 33990, 33991, 33992.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

***Note: In regard to related supply codes Q0508 (Miscellaneous supply or accessory for use with an implanted ventricular assist device) and Q0509 (Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A), authorization can be entered and supplies allowed. Please see DME Spreadsheet for Authorization Entry Guidelines.

SPECIAL NOTES

VAD implantation must be performed at a Medicare-approved heart transplant facility that has demonstrated competency in performing the procedure. The current list of approved facilities can be located at:

http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html

New York Heart Association (NYHA) Classification - The Stages of Heart Failure:
Class I - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
Class II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20—100 m). Comfortable only at rest.
Class IV - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

References:

1. Medicare National Coverage Determination (NCD) for Ventricular Assist Devices(ID# 20.9.1); Effective date10/30/2013; Accessed 8/24/21 via www.cms..gov.
2. Medicare NCA Tracking Sheet for Assist Devices as Destination Therapy (CAG-00119N); Accessed 8/24/21 via www.cms.gov.
3. Decision Memo for VAD for Bridge to Heart Transplantation; CAG-00432R, viewed online at www.cms.gov on 8/24/21.
4. Medicare Local Coverage Article (LCA) for Percutaneous Ventricular Assist Device (A53986); Effective date 10/1/2020; Accessed 8/24/21 via www.cms.gov/medicare-coverage-database .
5. Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N) Effective Date 12/1/20; Accessed 8/24/21 via www.cms.gov.
6. NYHA Functional Classification and Outcomes After Transcatheter Mitral Valve Repair in Heart Failure; JACC Journals: JACC Interventions; Archives, Vol.13, No. 20. https://www.jacc.org/doi/10.1016/j.jcin.2020.06.058?_ga=2.149168118.1191109192.1632425480-62389136.1632425480. Viewed on 9/24/21.

Policy Implementation/Update Information:

Revision Date: November 30, 2006: No criteria changes made.
Revision Date: June 17, 2009: New online policy format; no criteria changes made.
Revision Date: January 5, 2011 Indications For Coverage section: Updated Destination Therapy language under section c, item #1 with current CMS MM7220 language. Removed item #4 since this criterion was removed from MM7220. Reference section: Updated.
Revision Date: June 19, 2013; Annual Review; General Edits, updated codes.

Revision Date: October 31, 2013; National Coverage Determination; 20.9; updated language per new Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy; CAG -00432R); viewed online at www.cms.gov; 10/30/2013; Added transplant facility list.
Revision Date: April 16, 2014: Policy reviewed; Codes revised.
Revision Date: Annual Review. No changes to coverage criteria. Special Notes – removed web link for OPTN (bridge to transplant) as this is a link for member waitlist not for approved facilities. Reference section updated.
Revision Date: March 21, 2018; Annual Review; No CMS Updates. Minor Revisions Only.
Revision Date: March 20, 2019; CMS update to hyperlink for Approved facilities registry. Updated to https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html
Revision Date: January 20, 2021; CMS Update; Removed Indications for Coverage 3. B. "The member is active on the waitlist maintained by the Organ Procurement and Transplantation Network (OPTN)".
Revision Date: September 15, 2021; CMS Update; Restructured Indications for Coverage section to match new NCD formatting.
Revision Date: October 20, 2021; Staff Clarification: Updated Special Notes section to include Classification of Heart Failure.

Approval Dates:

Medical Coverage Policy Committee October 20, 2021

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