Ventricular Assist Devices
Clinical Coverage Criteria

Overview

Ventricular Assist Devices (VADs) or left ventricular assist devices (LVADs) are blood pumps that are implanted during a surgical procedure and attached to one or both ventricles. VADs are implanted in a weakened or damaged heart in order to assist the heart with pumping blood decreasing the work of the ventricle. VAD's are used as both a bridge to transplantation and as destination therapy.

The Centers for Medicare and Medicaid Services (CMS) initiated a National Coverage Analysis for Artificial Hearts and Related Devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy on February 3, 2020 (CAG-00453N). The Decision Memo for Artificial Hearts and Related Devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy was released on December 1, 2020 (CAG-00453N). Given new evidence in the peer-reviewed medical literature, CMS removed the NCD for Artificial Hearts and Related Devices (20.9), ending coverage with evidence development for artificial hearts and permitting Medicare coverage determinations for artificial hearts to be made by the Medicare Administrative Contractors (MACs) effective December 1, 2020. The NCD at Section 20.9.1 establishes conditions of coverage for VADs. In 1993, CMS first issued an NCD providing limited coverage of VADs and the policy has been expanded over the years. Effective December 1, 2020, CMS is also revising NCD 20.9.1 that provides coverage for ventricular assist devices for bridge-to-transplant and destination therapy. The decision is limited to durable, intracorporeal, left ventricular assist devices (LVADs), and does not include temporary VADs or extracorporeal membrane oxygen (ECMO).

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Ventricular Assist Devices (20.9.1). National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services, Inc. does not have an LCD or LCA for ventricular assist devices. (MCD search 02/08/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health requires prior authorization for ventricular assist devices. Medical records from the providers who have diagnosed or treated the symptoms prompting this request are also required.

Fallon Health Clinical Coverage Criteria

Criteria for destination therapy (all criteria must be met)

1. The device has been FDA approved for destination therapy.
2. The member has chronic end-stage heart failure as classified by New York Heart Association (NHYA) class IV (see table below) and is not a candidate for a heart transplant.
3. The member has failed to respond to maximum medical management such as:
   a. Beta-blockers or Ace Inhibitors for at least 45 of the last 60 days, or
   b. Has been balloon pump dependent for the 7 days, or
   c. Has been IV inotrope dependent for 14 days.
4. The member has a left ventricular ejection fraction (LVEF) less than 25%.
5. The member demonstrates functional limitations with peak oxygen consumption ≤ 14 ml/kg/min.

Criteria for bridge to transplantation (all criteria must be met)

1. The device must be FDA approved for bridge to transplantation.
2. The member is a candidate for a heart-transplant but is not expected to survive until transplantation without a VAD.

Medicare

Fallon Health follows coverage criteria in Medicare NCD for Ventricular Assist Devices (20.9.1) for Medicare members including Medicare Advantage, NaviCare and PACE plan members.

Policy References:
NCD link: **Ventricular Assist Devices (20.9.1)**

Manual References:
Claims Processing Instructions: **Claims Process Manual Chapter 32, Section 320.3**

Nationally Covered Indications

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. Effective for claims with dates of service on or after December 1, 2020, 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:
   - Have New York Heart Association (NYHA) Class IV heart failure; and

- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- 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:

- 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
- 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.

Plan members receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

The process for organizations to apply for CMS approval to be designated as a credentialing organization for VAD facilities is posted on the CMS web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: http://www.cms.gov/Medicare/Medicare-GeneralInformation/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html.

Nationally Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

This NCD does not address coverage of VADs for right ventricular support, biventricular support, use in plan members under the age of 18, use in plan members with complex congenital heart disease, or use in plan members with acute heart failure without a history of chronic heart failure. Coverage under in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

New York Heart Association (NYHA) Functional Classification

Class	Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.

IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Exclusions

- Any use of a ventricular assist device (VAD) other than described as covered above.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Removal of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal 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
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion
33999	Unlisted procedure, cardiac surgery

Replacement Accessories and Supplies for VADs (LVADs)
In rare instances it may be appropriate to pay for replacement of supplies and accessories for external VADs used by a plan member who is discharged from the hospital. Claims for replacement of supplies and accessories used with an external VAD are covered under the medical benefit and not the durable medical equipment benefit. Refer to Medicare Claims Processing Manual, Chapter 32, Section 320.3.4– Replacement Accessories and Supplies for External VADs or Any VAD for claims coding.

References

1. CMS: National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9). Effective Date of this Version 10/30/2013. Note: As a result of a reconsideration, effective December 1, 2020, Artificial Hearts and Related Devices (20.9) has been removed from the NCD Manual. Effective for claims with dates of service on or after December 1, 2020, coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors (CAG-00453N).
2. Kherani AR, Oz MC. Ventricular assistance to bridge to transplantation. Surg Clin North Am. 2004 Feb;84(1):75-89, viii-ix.

3. Park SJ, Tector A, Piccioni W et al. Left ventricular assist devices as destination therapy: a new look at survival. J Thorac Cardiovasc Surg 2005; 129(1):9-17.
4. Lietz K, Long JW, Kfoury AG, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. Circulation. 2007 Jul 31;116(5):497-505.
5. Esmore D, Kaye D, Spratt P, et al. A prospective, multicenter trial of the VentrAssist left ventricular assist device for bridge to transplant: safety and efficacy. J Heart Lung Transplant. 2008 Jun;27(6):579-88.
6. Boothroyd LJ, Lambert LJ, Sas G, Should eligibility for heart transplantation be a requirement for left ventricular assist device use? Recommendations based on a systematic review. Can J Cardiol. 2013 Dec;29(12):1712-20.
7. Kirklin JK, Naftel DC, Pagani FD, et al Long-term mechanical circulatory support (destination therapy): on track to compete with heart transplantation? J Thorac Cardiovasc Surg. 2012 Sep;144(3):584-603; discussion 597-8.
8. Stone M, Hinchey J, Sattler C, Evans A. Trends in the Management of Patients With Left Ventricular Assist Devices Presenting for Noncardiac Surgery: A 10-Year Institutional Experience. Semin Cardiothorac Vasc Anesth. 2015 Dec 17.
9. John R, Holley CT, Eckman P, et al. A Decade of Experience With Continuous-Flow Left Ventricular Assist Devices. Semin Thorac Cardiovasc Surg. 2016 Summer;28(2):363-375.
10. Shaw SM, Venkateswaran R, Hogg R, et. al. Durable left ventricular assist device support as a bridge to heart transplant candidacy. Interact Cardiovasc Thorac Surg. 2018 Oct 22.
11. Pal N, Stansfield J, Mukhopadhyay N, Nelson M. Marginal Improvement in Survival Post-Heart Transplantation in Patients With Prior Left Ventricular Assist Device: A Temporal Analysis of United Network of Organ Sharing Registry. J Cardiothorac Vasc Anesth. 2019 Oct 10.
12. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). Effective Date of this Version 12/01/2020. Accessed 02/08/2022.

Policy history

Origination date:	02/01/2016
Approval(s):	Technology Assessment Committee: 1/27/2016 (new policy), 01/25/2017 (updated references), 01/24/2018 (annual review), 01/23/2019 (updated references), 01/22/2020 (updated references) *02/08/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section*

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.