Ventricular Assist Devices
Clinical Coverage Criteria

Overview

Left ventricular assist devices (LVADs) are designed to take over the function of the weakened heart's left ventricle, which delivers oxygenated blood from the heart to the body. The LVAD is surgically implanted in the patient's chest by a trained cardiac surgeon. A tube placed in the left ventricle diverts blood from the heart to the LVAD pump. The pump then propels the blood back into the aorta and out to the rest of the body. This is also known as mechanical circulatory support. Once the LVAD is in place, a driveline is passed through the skin of the abdomen and connected to the controller and a power supply. LVAD's are used as both a bridge to transplantation and as destination therapy. People can leave the hospital setting with the implanted device and return to activities of normal life with some restrictions.

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:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization is required for insertion, replacement and removal of ventricular assist devices. This prior authorization is separate from any prior authorization that may be required for the member's inpatient hospital encounter.

Prior authorization is required for replacement VAD supplies and accessories.

Fallon Health Clinical Coverage Criteria

Left Ventricular Assist Devices
Fallon Health Clinical Coverage Criteria for left ventricular assist devices apply to MassHealth ACO and Community Care members.

Effective for dates of service on or after September 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for insertion of left ventricular assist devices for MassHealth ACO and Community Care members.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:
- InterQual® CP:Procedures, Left Ventricular Assist Device (LVAD) Insertion

Note: InterQual® Criteria do not cover the insertion of a percutaneous left ventricular assist device used to protect the heart during invasive procedures or a temporary LVAD for short-term mechanical circulatory support while treatment decisions are made.

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Percutaneous Ventricular Assist Devices
Fallon Health Clinical Coverage Criteria for percutaneous ventricular assist devices apply to all products.

Percutaneous ventricular assist devices (pVADs) may be considered medically necessary when the following criteria are met:
1. The requested pVAD is FDA-approved device and intended use is in accordance with FDA-labeled indications.
2. The member meets one of the following clinical indications:
    a. The member has ongoing cardiogenic shock that occurs less than 48 hours following acute myocardial infarction or open-heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (includes volume loading and use of pressors and inotropes, with or without IABP).[1]
    b. The member requires temporary (≤ 6 hours) ventricular support for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of a percutaneous ventricular assist device in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Right Ventricular Assist Devices
Fallon Health Clinical Coverage Criteria for right ventricular assist devices apply to all products.

The Impella RP and Impella RP Flex System with SmartAssist may be medically necessary for up to 14 days for members meeting the following criteria:
1. The member has a body surface area ≥ 1.5 m2, and

[1] The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD Catheters, in conjunction with the Automated Impella Controller (collectively, Impella System), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD).

2. The member has acute right heart failure or right heart failure decompensation that is not responsive to optimal medical management following:
   a. Left ventricular assist device (LVAD) implantation; **or**
   b. Cardiogenic shock due to acute MI, or
   c. Heart transplant, or
   d. Open-heart surgery.

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.

INTERMACS Clinical Profiles

INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) profiles were created to provide prognostic data for patients with advanced heart failure receiving mechanical support. INTERMACS profiles are commonly used to describe disease severity and are classified using 7 profiles plus 3 modifiers. The 3 modifiers (arrhythmia, temporary circulatory support, and frequent flyer) were added to characterize profiles needing further delineation (Stevenson et al., *J Heart Lung Transplant*. 2009, 28: 535-41).

Profile 1: Critical cardiogenic shock	Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels. “Crash and burn.”
Profile 2: Progressive decline	Patient with declining function despite intravenous inotropic support, may be manifest by worsening renal function, nutritional depletion, inability to restore volume balance “Sliding on inotropes.” Also describes declining status in patients unable to tolerate inotropic therapy.
Profile 3: stable but inotrope dependent	Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support (or a temporary circulatory support device or both) but demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction “Dependent stability.”
Profile 4: Resting symptoms	Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during ADL. Doses of diuretics generally fluctuate at very high levels. More intensive management and surveillance strategies should be considered, which may in some cases reveal poor compliance that would compromise outcomes with any therapy. Some patients may shuttle between 4 and 5.
Profile 5: Exertion intolerant	Comfortable at rest and with ADL but unable to engage in any other activity, living predominantly within the house. Patients are comfortable at rest without congestive symptoms, but may have underlying refractory elevated volume status, often with renal dysfunction. If underlying nutritional status and organ

	function are marginal, patient may be more at risk than INTERMACS 4, and require definitive intervention.
Profile 6: Exertion limited	Patient without evidence of fluid overload is comfortable at rest, and with activities of daily living and minor activities outside the home but fatigues after the first few minutes of any meaningful activity. Attribution to cardiac limitation requires careful measurement of peak oxygen consumption, in some cases with hemodynamic monitoring to confirm severity of cardiac impairment. "Walking wounded."
Profile 7: Advanced NYHA III	A placeholder for more precise specification in future, this level includes patients who are without current or recent episodes of unstable fluid balance, living comfortably with meaningful activity limited to mild physical exertion.

Modifiers for INTERMACS Profiles

- TCS-Temporary Circulatory Support can modify only patients in hospital (other devices would be INTERMACS devices) Includes IABP, ECMO, TandemHeart, Levitronix ,BVS 5000 or AB5000, Impella.
- A-Arrhythmia –can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to clinical compromise. This includes frequent ICD shock or requirement for external defibrillator, usually more than twice weekly.
- FF-Frequent Flyer – can modify only outpatients, designating a patient requiring frequent emergency visits or hospitalizations for diuretics, ultrafiltration, or temporary intravenous vasoactive therapy.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for ventricular assist devices. Medicare has an NCD for Ventricular Assist Devices (20.9.1). National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area does not have an LCD ventricular assist devices (MCD search 07/21/2025).

Nationally Covered Indications for ventricular assist devices include (1) Post-cardiotomy, and (2) 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 criteria in the NCD.

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 (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

Note: This NCD does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

Link: Ventricular Assist Devices (20.9.1) Version 2, Effective Date of this Version 12/01/2020

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for ventricular assist devices (MassHealth website search 07/21/2025), therefore, the Plan's coverage criteria are applicable.

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.

Left ventricular assist devices

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
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report

Percutaneous ventricular assist devices

Per the manufacturer (Abiomed), the Impella® Heart Device/ Circulatory Support System is a minimally invasive percutaneous catheter-based support device, designed to provide partial circulatory support. The Impella® is not a left ventricular assist device designed to provide transition to transplant; it is designed to assist during revascularization procedures for a short term (6-8 hours).

Use CPT code 33990 or 33991 as appropriate, for percutaneous left ventricular assist device insertion. For removal or repositioning of the device, use CPT code 33992 or 33993 only when performed at a separate and distinct session from insertion. Otherwise, these procedures are bundled into the fee schedule allowance for insertion.

For percutaneous right ventricular assist insertion, use CPT code 33995. For removal performed at a separate and distinct session, use CPT code 33997. Note CPT codes 33995 and 33997 are nonpayable for MassHealth ACO members (MassHealth Physician Manual Subchapter 6 PHY-170 effective 08/01/2024).

Code	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannulas), at separate and distinct session from insertion

33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

Coverage for VAD accessories and supplies furnished at the time of implant
The VAD device itself should be charged as a line item on the inpatient bill under Revenue Code 278 (Other Implants), which identifies it as an implantable prosthetic device. As with any item, the hospital should set its charge pursuant to hospital protocol and policy. VAD accessories and supplies are necessary for the function of the implanted VAD device itself. The initial VAD supplies and accessories that go home with the patient should be charged as a line item on the inpatient bill under Revenue Code 274 (Prosthetic/Orthotic Devices). All of these items are reimbursed as part of the MS-DRG payment for the implant admission. The VAD accessories are not considered Durable Medical Equipment (DME).

Coverage for replacement VAD supplies and accessories
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. HCPCS codes for LVAD accessories and supplies fall under the prosthetics benefit category.

CMS has determined that the reasonable useful lifetime for code Q0477 thru Q0495, Q0497-Q0502, and Q0504 thru Q0509 to be one year (R3931CP).

Please note that when determined to be medically necessary, dressings used with VADs are covered under the prosthetic device benefit as a supply necessary for the effective use of the VAD/prosthetic device. Claims for dressings necessary for the effective use of a VAD should be billed using the appropriate miscellaneous VAD supply code (MM7888; R1159OTN).

Note: HCPCS codes Q0477 thru Q0495, Q0497-Q0502, and Q0504 thru Q0509 are nonpayable for MassHealth ACO members (MassHealth Prosthetics Manual Subchapter 6 PRT-29 effective 01/01/2024).

Code	Description
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular device, replacement only
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
Q0479	Power module for use with electric/pneumatic ventricular assist device, replacement only
Q0480	Driver for use with pneumatic ventricular assist device, replacement only
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only
Q0482	Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only
Q0484	Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0485	Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only
Q0486	Monitor control cable for use with electric ventricular assist device, replacement only

Q0487	Leads (pneumatic/electrical) for use with any type of electric/pneumatic ventricular assist device, replacement only
Q0488	Power pack base for use with electric ventricular assist device, replacement only
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only
Q0490	Emergency power source for use with electric ventricular assist device, replacement only
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only
Q0492	Emergency power supply cable for use with electric ventricular assist device, pneumatic only
Q0493	Emergency power supply cable for use with electric/pneumatic ventricular assist device, pneumatic only
Q0494	Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0496	Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0499	Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only
Q0500	Filters for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0502	Mobility cart for pneumatic ventricular assist device, replacement only
Q0503	Battery for pneumatic ventricular assist device, replacement only
Q0504	Power adapter for pneumatic ventricular assist device, replacement only, vehicle type
Q0506	Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0507	Miscellaneous supply or accessory for use with an external ventricular assist device
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A

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).
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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.
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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.
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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.
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12. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). Effective Date of this Version 12/01/2020. Accessed 02/08/2022.
13. Stevenson LW, Pagani FD, Young JB, et al. INTERMACS profiles of advanced heart failure: The current picture. *J Heart Lung Transplant*. 2009 Jun;28(6):535-41.
14. AbioMed. Impella® Heart Pump Coding and Billing Guide. July 2024. Available at: https://www.heartrecovery.com/en-us/resources/downloads/guide-reimbursement-coding-and-billing.

Policy history

Origination date:	02/01/2016
Review/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), 08/27/2024 (annual review, adopted InterQual criteria, updated Coding section), 07/22/2024 (annual review, added criteria for percutaneous ventricular assist devices and right ventricular assist devices). Utilization Management Committee: 08/19/2025 (annual review, approved with addition of criteria for percutaneous ventricular assist devices and right ventricular assist devices).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may

create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

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.

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