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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Left Ventricular Assistive Devices (LVAD) Policy

Indication/Usage:

A ventricular assist device (VAD), also known as a heart pump, is a mechanical circulatory device that helps pump blood from the lower chambers of the heart to the rest of the body for members who have reached end stage heart failure. A VAD is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Surgically implanted, the LVAD, a battery-operated, mechanical pump, which then helps the left ventricle (main pumping chamber of the heart) pump blood to the rest of the body. LVADs can be used as:

- Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy.

- Bridge-to-transplant therapy: This is a life-saving therapy for patients awaiting a heart transplant. Patients use the LVAD until a heart becomes available. In some cases, the LVAD is able to restore the failing heart, eliminating the need for a transplant.

- Destination therapy: Some patients are not candidates for heart transplants. In this case, patients can receive long-term treatment using an LVAD, which can prolong and improve patients' lives.

Medical Indications for Authorization Commercial Members

SummaCare considers a Food and Drug Administration (FDA)-approved ventricular assist device (VAD) medically necessary for any of the following FDA-approved indications

1. Post-cardiotomy VAD's 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. As a bridge to transplant for members who are awaiting heart transplantation and the device has received FDA approval for a bridge to transplant indication (e.g., HeartMate 3 left ventricular assist system (LVAS))

3. As destination therapy when all of the following criteria are met:

    - The device has received FDA approval for a destination therapy indication (e.g., HeartMate II LVAD, HeartWare HVAD)
    - Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not a candidate for heart transplant
    - Member has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or has been IV inotrope dependent for 14 days
    - Has a left ventricular ejection fraction (LVEF) less than 25 %
    - Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min.

This criterion may be waived in persons who are dependent on a balloon pump (IABP) or similar temporary mechanical circulatory support or intravenous inotrope dependent or are otherwise unable to perform exercise stress testing.

SummaCare considers FDA-approved pediatric VADs medically necessary when both of the following criteria are met:

- Child has documented end-stage left ventricular failure; *and*
- An age and size-appropriate VAD will be used until a donor heart can be obtained

This policy does not address coverage of VADs for right ventricular support, biventricular support and SummaCare considers VADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature

Medicare Members CMS

NCD ID 20.9.1 Ventricular Assist Devices Item/Service Description

A. General

A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

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. 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.

Beneficiaries 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.

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

CPT /HCPCS covered by this policy

- 33975, 33976, 33979
- 33979 Insertion of VAD, implantable, intracorporeal, single ventricle
- 33980 Removal of VAD, implantable, intracorporeal, single ventricle
- 3982 Replacement of VAD pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
- 33983 Replacement of VAD pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
- 93750 Interrogation of VAD, in person, with physician analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report
- Q0477 Power module patient cable
- Q0479 power module, MPU
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- Q0481 Pocket controller, EPC
- Q0495 Universal battery charger
- Q0496 Power module backup battery
- Q0497 14- Volt Li-ion battery clip, each
- Q0498 HeartMate GoGear holster or holster vest
- Q0499 HeartMate GoGear or pocket controller consolidated bag
- Q0501 HeartMate GoGear shower bag
- Q0506 14- Volt Li-ion battery, each
- Q0508 Driveline Stabilization system supplies, Pocket controller wearable accessory kit
- Q0509 Anything provided for a Medicare patient who was not Medicare on implant

Limitations

SummaCare considers all other indications for the use of LVADs not otherwise listed above remain experimental and investigational because the efficacy has not been proven.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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