Clinical Policy: Ventricular Assist Devices

Reference Number: IL.CP.MP.512 Coding Implications
Last Review Date: 09/21 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ventricular assist devices (VAD's), including Left Ventricular Assist Devices (LVAD's) are used to sustain patients awaiting heart transplantation and to facilitate cardiac recovery in patients suffering from reversible cardiac dysfunction. Patients with VADs are classified by the United Network for Organ Sharing (UNOS) as Status I, that is, persons who are most ill and are considered the highest priority for transplant. The median duration for time on the device is between 20 and 120 days.

These devices can be used as:

- Bridge to cardiac transplantation
- Bridge to decision (regarding transplant eligibility)
- Destination therapy
- Bridge to recovery of heart function

To date, there are three implantable LVADs approved by the FDA:

- The HeartMate II Left Ventricular Assist System
- HeartMate III Left Ventricular Assist System
    - Both manufactured by Thoratec Corporation, approved for BTT in 2008 and DT in 2010.
- The HeartWare Ventricular Assist System HVAD
    - Manufactured by HeartWare, Inc., approved only for BTT in 2012.

Ventricular Assist Device (VAD)	Used to assist a damaged or weakened heart in pumping blood. The device is surgically attached to one or both intact ventricles and is used to support circulation in patients with decompensating advanced heart failure who fail to improve or stabilize with optimal medical therapy. Most patients will receive a left ventricular assist device but some will require left plus right ventricular support (biventricular support or BiVAD).
Bridge to Decision	A final decision regarding transplantation eligibility has not been able to be reached. The member is being treated with inotropic agents and /or intra-aortic balloon pump but has secondary end organ dysfunction or other potentially reversible medical conditions which may be temporary contraindications to cardiac transplantation. Mechanical support with a VAD may be able to reverse the contraindication.
Destination Therapy	Long-term use of the device as an alternative to transplantation in patients with end stage hear failure who are considered ineligible for transplantation
Bridge to recovery	LVAD unloading can promote recovery of myocardial function that is sufficient to allow device removal without cardiac transplantation. These

	devices have usually been placed as a bridge to transplant or destination therapy.
Total Artificial Heart	A device that replaces the two lower chambers of the heart and is available to individuals with end-stage heart failure.

Policy/Criteria

It is the policy of MeridianHealth affiliated with Centene Corporation® that ventricular assist devices are **medically necessary** for the following indications:

I. **Left Ventricular Devices**
   A. Left Ventricular Assist Devices, are considered for coverage through Meridian Health Plan in the following circumstances:
      i. As a ***bridge to transplantation*** for patients who meet **all** of the following criteria:
         1. Is approved for heart transplant(see criteria for heart transplantation MHP policy F.22) and listed for heart transplant at an approved facility.
         2. Has irreversible, terminal heart disease and are not expected to survive until a donor heart can be obtained
         3. Has heart disease that is not amenable to other medical intervention or surgical procedure that would confer an equal survival advantage to heart transplantation
         4. Symptoms of advanced heart failure consistent with NYHA class IV limitations despite optimal medical management, requiring the initiation of inotropic therapy and / or intra-aortic balloon pump for **one** of the following:
            a. Hemodynamic instability (left atrial pressure or pulmonary capillary wedge pressure >20 mmHg with either:
               i. SBP <80 mmHg or cardiac index <2.0L/min/m2 ***or***
               ii. heart rate > 120 beats/min)
            b. Evidence of progressive organ dysfunction despite stable hemodynamic measurements
            c. Life-threatening ventricular arrhythmias with contraindications to inotrope therapy
      ii. For ***short-term use*** (generally less than 2 weeks) in patients who present with cardiogenic shock with hemodynamic instability (left atrial pressure or pulmonary capillary wedge pressure >20 mmHg with **one** of the following:
         1. SBP <80 mmHg or cardiac index <2.0L/min/m2
         2. heart rate > 120 beats/min despite optimal medical management including the use of inotrope therapy and an intra-aortic balloon pump when there is a likelihood of myocardial recovery.
      iii. As ***destination therapy*** when **all** of the following criteria are met:
         1. The device has received FDA approval for a destination therapy indication; and

2. Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not a candidate for heart transplant
3. 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
4. Has a left ventricular ejection fraction (LVEF) less than 25 %
5. Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min. (Note: This criterion may be waived in persons who are unable to perform exercise stress testing).

iv. ***Pediatric patient***s; TheCurrent FDA-approved pediatric VADs include the Berlin Heart EXCOR Pediatric Ventricular Assist Device (for children aged 16 years or younger and up to 60 kg in weight) and the HeartAssist 5 Pediatric Ventricular Assist Device (for children aged 5 to 16 years with BSA greater than or equal to 0.7 m2 and less than 1.5 m2) which are covered as a bridge to cardiac transplantation in children when used in accordance with the FDA's Humanitarian Device Exemption (HDE) requirements when **all** of the following criteria are met:

1. In NYHA Class IV end-stage heart failure (left ventricular or biventricular)
2. Refractory to medical therapy
3. Listed candidate for cardiac transplantation
4. None of the following contraindications
    a. Patients suffering from right ventricular failure unresolved by medical therapy
    b. Patients with a primary coagulopathy or platelet disorders such as hemophilia or Von Willebrand's disease
    c. Have a known allergy or sensitivity to the blood thinner heparin
    d. Prior surgery where apical cannulation, pump replacement or graft anastomosis is not feasible
    e. Have anatomical anomalies that would prevent surgical connection of the outflow graft to the ascending aorta

II. Right Ventricular Assist Devices

A. MHP considers FDA-approved right ventricular assist devices (RVADs; e.g., the CentriMag Right Ventricular Assist System) medically necessary for temporary circulatory support when **both** of the following criteria are met:
    i. RVAD is used for up to 30 days for members in cardiogenic shock due to acute right ventricular failure
    ii. Member is willing and able to be treated with heparin or an appropriate alternative anti-coagulant.

B. MHP considers RVADs experimental and investigational when criteria are not met.

III. Percutaneous Left Ventricular Assist Devices

A. MHP considers a FDA-approved percutaneous left ventricular assist device (pVAD) (e.g., the TandemHeart and the Impella) medically necessary for **one** of the following indications:
   i. Providing short-term circulatory support in cardiogenic shock
   ii. Bridge to transplant
   iii. Acute MI
   iv. Ongoing cardiogenic shock that occurs less than 48 hours following acute MI or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional measures
   v. As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk patients:
      1. Persons undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35 %; ***or***
      2. Persons with three vessel disease and ejection fraction less than 30 %

B. MHP considers pVADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

IV. Percutaneous Right Ventricular Assist Devices

A. MHP considers a FDA-approved percutaneous left ventricular assist device (Impella RP system) medically necessary for the following indications:
   i. Acute right heart failure or decompensation following LVAD implantation, MI, heart transplant or open heart surgery

V. Artificial Hearts:

A. Bridge to Transplant: An FDA-approved total artificial heart (e.g., CardioWest Total Artificial Heart), is a covered benefit when used as a bridge to transplant for transplant-eligible members who are at imminent risk of death (NYHA Class IV) due to biventricular failure who are awaiting heart transplantation.
B. Member is on maximal IV inotropic support/medical management.

VI. Network

A. Requesting facilities must be CMS approved.
B. Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).
C. By March 27, 2009, all facilities must meet the above facility criteria and be credentialed by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007).
D. VADs used as a bridge to transplantation, implanted at a site other than the Medicare-approved transplant center, must meet the following CMS criteria and language: "The implanting site, if different than the Medicare approved transplant center, must receive written permission from the Medicare approved heart transplant center under which the patient is listed prior to implementation of the VAD."

VII. Absolute Contraindications

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A. Use of a non-FDA approved or cleared ventricular assist device, or an FDA approved device for a non-approved or off-label indication, is considered investigational.
B. A VAD is ***not covered*** if any of the following conditions are present, (non-covered conditions are not limited to this list):
    i. Irreversible multiple organ dysfunction
    ii. Severely restricted pulmonary function
    iii. Major neurological deficit
    iv. Cerebral vascular accident with significant cognitive impairment
    v. Active, systemic infection
    vi. Malignancy expected to significantly limit future survival
    vii. Long-term high-dose corticosteroid use
    viii. Presence of HIV infection
        1. [1] Absence of HIV infection is defined by all of the following:
            a. CD4 count greater than 200 cells/mm^3 for more than 6 months; *and*
            b. HIV-1 RNA (viral load) undetectable; *and*
            c. On stable anti-viral therapy for more than 3 months; *and*
            d. No other complications from AIDS, such as opportunistic infection (e.g., aspergillus, coccidiomycosis, resistant fungal infections, tuberculosis), Kaposi's sarcoma or other neoplasm.
    ix. Blood clotting disorders
    x. Age >70 years
    xi. Aortic aneurysm surgery
    xii. Cardiogenic shock not related to cardiac surgery
    xiii. Noncompliance
C. MHP does not cover the use of mesenchymal precursor cells as adjunctive therapy in recipients of ventricular assist devices experimental and investigational because the effectiveness of this approach has not been established.

[1] (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
N/A	

HCPCS ®* Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
N/A	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date		9/29/10
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Appendix A:

Table: New York Heart Association (NYHA) Functional Classification of Heart Failure

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

Source: New York Heart Association, 1994.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.