OHCA Guideline

Medical Procedure Class:	Ventricular Assist Device
Initial Implementation Date:	12/01/2017
Last Review Date:	03/29/2021
Effective Date:	05/06/2021
Next Review/Revision Date:	05/01/2024

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☐ New Criteria ☒ Revision of Existing Criteria

Summary

Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Bridge to Transplant – An indication for an assist device where the recipient is a candidate for a heart transplant, is awaiting a donor heart for transplant, and is not expected to live to transplant without an assist device.

Destination Therapy – Use of an assist device for a patient who has end-stage heart disease, is NOT a candidate for heart transplant for any reason, and the assist device is intended to extend life without transplant.

Mechanical Circulatory Assist Devices - Devices designed to augment cardiac output in the weakened native heart or the heart temporarily in arrest for inter-operative procedure. Included are cardiopulmonary bypass, ventricular assist devices, and intra-aortic balloon pumps. Unlike total artificial hearts, not included in this group, the native heart is NOT removed.

Ventricular Assist Device (VAD) – A mechanical pump designed to assist the weakened ventricle in augmenting cardiac output. Multiple designs are available.

Left Ventricular Assist Device (LVAD) – A mechanical pump designed to assist the weakened left ventricle. Such a device takes blood from the left ventricle via an implanted cannula and pumps it into the aorta via an implanted cannula.

Right Ventricular Assist Device (RVAD) - A mechanical pump designed to assist the weakened right ventricle. Such a device takes blood from the right ventricle via an implanted cannula and pumps it into the pulmonary artery via an implanted cannula.

Biventricular Assist Device (BiVAD) - A mechanical pump designed to assist both weakened ventricles. Such a device combines the features of both LVAD and RVAD.

Percutaneous Ventricular Assist Device (pVAD) – A mechanical device utilizing a catheter inserted via 1) a large peripheral artery (usually femoral) into the left ventricle, with a pump in the distal end of the catheter which extracts blood from the left ventricle pumping it into the aorta via a more proximal catheter opening located in the aorta, OR 2) a large peripheral vein into the right

atrium, puncturing the interatrial septum to extract blood from the left atrium, and then returning the blood to the abdominal aorta via a second catheter in the femoral artery.

New York Heart Association (NYHA) Classification IV – Patients with cardiac disease resulting in inability to carry on any physical activity. They are comfortable at rest. Less than ordinary activity cause fatigue, palpitation, dyspnea, or anginal pain.

Description

A ventricular assist device (VAD) is a mechanical pump that 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. These devices are used for the support of blood circulation post-cardiotomy (the period following open heart surgery), as a bridge to transplant, or as destination therapy.
There are many VAD's available for use. Typically, short term devices are extracorporeal (located outside the body) and long term devices are implantable systems. LVAD's are the more commonly used device. They provide blood flow throughout the entire body while the RVAD's primarily support the pulmonary circulation.

CPT Codes Covered Requiring Prior Authorization (PA)

33975—Insertion of VAD, extracorporeal , single ventricle
33976—Insertion of VAD, extracorporeal, biventricular
33979—Insertion of VAD, implantable intracorporeal, single ventricle
33981—Replacement of extracorporeal VAD, single or biventricular, pump(s), single or each pump
33982—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
33990—Insertion of VAD, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
33991—Insertion of VAD, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
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
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

Approval Criteria

I. GENERAL

A. Medical Necessity must be met, all documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service in accordance with the OAC 317:30-3-1 (f) (2) referenced above under the heading of definitions.

B. All VADs must be used in accordance with FDA labeling instructions and criteria; AND must be approved for the indicated use.

C. All VADs used must be approved as age appropriate.

D. All documentation must be easily legible.

II. INDICATIONS

A. **Initial Placement, VAD, Post-cardiotomy**

1. Member is immediate post-cardiotomy, the period following open-heart surgery and requires the VAD for support of blood circulation, **AND**
2. Device planned for implantation is FDA approved for this indication and age appropriate for the member, and the device intended is identified in the documentation provided.

B. **Initial Placement, LVAD (Bridge to Transplantation)**

Must meet **ONE** of the following:

1. Member is a potential transplant candidate who has a relative contraindication(s) to transplantation where there is a reasonable chance that this contraindication can be improved by use of a VAD and that transplantation candidacy can be reached by use of the VAD, **OR**
2. Member is in the process of evaluation for heart transplant with a diagnosed heart disease that is not amenable to another surgical procedure conferring equal survival to heart transplantation, and documentation states that probability of achieving transplantation candidacy on completion of evaluation is high,

AND, ALL of the following:

3. VAD is determined to be necessary for sustaining life until a suitable donor heart is available, **AND**
4. Device planned for implantation is FDA approved for this indication and age-appropriate for the member, and the device intended is identified in the documentation provided, **AND**
5. The device is to be surgically implanted at a center approved by Medicare to perform these procedures.

B. **Initial Placement, LVAD, (Destination Therapy)**

Must meet **ALL** of the following:

1. Member must have completed workup to determine that member is NOT a candidate for heart transplantation, **AND**
2. Must meet the specified clinical criteria of services provided at an FDA approved facility, **AND**
3. Workup has determined that mechanical support is required to support life as evidenced by the following:
   a. Must meet New York Heart Association (NYHA) Class IV end-stage ventricular heart failure criteria, **AND**
   b. Are inotrope dependent **OR** have a cardiac index (CI), <2.2 L/min, while not on inotropes, **AND**
   c. Member has failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days or have been balloon pump dependent for 7 days, or IV inotrope-dependent for 14 days, **AND**
   d. Must have a left ventricular ejection fraction (LVEF) of <25%, **AND**
   e. Must have demonstrated functional limitation with a peak oxygen consumption ≤14 ml/kg/min (may be waived for members who are balloon pump dependent, or IV inotrope dependent, or otherwise are clearly unable to perform exercise stress testing), **AND**
4. Device planned for implantation is FDA approved for this indication and age-appropriate for the member, and the device intended is identified in the documentation provided.

C. **Initial Placement, RVAD**

Must meet **BOTH** of the following:

1. RVAD may be medically necessary for temporary circulatory support for up to 30 days for members in cardiogenic shock due to acute (R) ventricular failure, **AND**
2. Member is willing and able to be treated with heparin or an appropriate alternative anti-coagulant.
3. Device planned for implantation is FDA approved for this indication and age appropriate for the member, and the device intended is identified in the documentation provided.

D. **Initial Placement, pVAD**

Must meet **ONE** of the following:

1. As a short-term circulatory support for acute cardiogenic shock resulting from a LVAD placement, Myocardial Infarction (MI), heart transplant, open heart surgery, or similar circumstance, OR
2. As an adjunct to percutaneous coronary intervention (PCI) in high-risk members undergoing:
    a. unprotected left main or last-remaining conduit PCI with ejection fraction less than 35%, OR
    b. members with three vessel disease and ejection fraction less than 30%.

III. FREQUENCY

Replacement VAD's are covered if the above criteria were met at the time of implantation.

IV. VAD SUPPLIES

1. A contracted qualified health professional (M.D., D.O., P.A., C.N.P., A.R.N.P.) must request the supplies by completing a prescription which includes the following:
    - Date of Order
    - Name of prescriber
    - Name and address of the member
    - Member ID#
    - Number of kits to be dispensed
    - Prescriber's signature
2. Member must have had previously approved Ventricular Assist Device (VAD) procedure as evidenced by medical record submission.
3. Coverage Limitations for supplies:
    a. MAX Approval Limit = 12 dressing change kits per month **OR** 3x per week; up to 6 months
    b. Any request greater than this limit requires physician review for medical necessity.

****NOTE:** Additional information may be required after initial review.**

Additional Information

Non-Covered Items:

1. Total Artificial Hearts are not covered.
2. VADs are not covered if any of the following conditions are present:
    a. Irreversible multiple organ dysfunction, including advanced kidney disease likely to

progress to dialysis
   b. Severely restricted pulmonary function
   c. Major neurological deficit
   d. History of CVA with significant cognitive dysfunction
   e. Active, systemic infection
   f. Active malignancy except for localized basal cell carcinoma
   g. Long-term high dose corticosteroid use
   h. HIV seropositivity,
   i. Irreversible blood clotting disorders
3. Separate supplies not included in VAD Kit, related to the care of the Ventricular Assist Device (VAD) are not reimbursed.

References

1. Oklahoma Health Care Authority; Policies & Rules, OAC 317: 30-3-1
2. CMS National Coverage Determination (NCD), Ventricular Assist Devices (VADs) 20.9.1 (REVISED)
3. CMS Decision Memo for Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N), Effective date 12/01/20. Retrieved 03/26/21 from: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=298&NCDId=246&ncdver=6&IsPopup=y&bc=AAAAAAAACAAA&
4. Blue Cross Blue Shield of NC, Medical Coverage Policy, 01/20/21
5. Cigna Medical Coverage Policy: Ventricular Assist Devices (VADs), Percutaneous Cardiac Support Systems and Total Artificial Heart. Coverage Policy Number 0054, 12/15/2020
6. United Healthcare® Medicare Advantage Policy Guideline, Ventricular Assist Devices (NCD 20.9.1), #MPG343.07, 12/09/20