OHCA Guideline

Medical Procedure Class:	**Ventricular Assist Device**
Initial Implementation Date:	12/01/2017
Last Review Date:	8/14/20255
Effective Date:	11/1/2025
Next Review/Revision Date:	November 2028

* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.

☐ 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 (authorization through InterQual)
33976—Insertion of VAD, extracorporeal, biventricular (authorization through InterQual)
33979—Insertion of VAD, implantable intracorporeal, single ventricle (authorization through InterQual)
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, pVAD

1. Must meet ONE of the following:
   a. 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
   b. As an adjunct to percutaneous coronary intervention (PCI) in high-risk members undergoing:
      - unprotected left main or last-remaining conduit PCI with ejection fraction less than 35%; OR
      - members with three vessel disease and ejection fraction less than 30%.

B. **Replacement of VAD**

1. Documentation must support the following:
   a. Initial requirements for VAD placement were met; AND
   b. Member still requires the cardiac support of a ventricular assist device; AND
   c. Current device is insufficient to meet member's needs or is malfunctioning; AND.
   d. Reason(s) why device must be replaced.

II. <u>VAD SUPPLIES</u>

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.

Non-Coverage

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; 30-5-Part 17 Medical Suppliers
2. CMS National Coverage Determination (NCD), Ventricular Assist Devices (VADs) 20.9.1 (Revised Implementation Date 07/27/2021)
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. NCA - Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N) - Decision Memo