OHCA Guidelines

Medical Procedure Class:	Ventricular Assist Device
Implementation Date:	12/1/17
Review/Revision Date:	
Chief Medical Officer (CMO) Signature/Date:	[signature] for the CMO 10/18/17
Director Medical Authorization and Review (MAR) Signature/Date:	[signature] CPC 10-18-17
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* 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.

Definition:

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.

Temporary Indications - Include post-cardiotomy and inability to wean from Cardio-Pulmonary Bypass (CAPB), acute coronary syndrome with cardiogenic shock, etc.

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 (BVAD) - 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.

CPT and ICD-10 PCS Codes Covered:	
CPT 33975, 33976, 33979, 33981, 33982, 33983, 33990, 33991 and 33993 **PCS** 02HA0QZ, 02HA3QZ, 02HA4QZ, 02HA0RS, 02HA0RZ, 02HA3RS, 02HA3RZ, 02HA4RS and 02HA4RZ	Refer to CPT or ICD-10 PCS for complete definition of covered codes.

Non Covered Items:

1. Total Artificial Hearts are not covered.
2. VADs are not covered if <u>any</u> 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

Approval Criteria:

1. 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.
2. All VADs must be used in accordance with FDA labeling instructions and criteria, and must be approved for the indicated use.
3. All VADs used must be approved as age appropriate.
4. All documentation must be easily legible.

A. Initial Placement, LVAD, (Bridge to Transplantation) (Must meet <u>one</u> of 1 - 3, and <u>all</u> of 4 - 7.)

<u>ONE</u> of the following: (1 – 3):

1. Currently listed as a candidate for heart transplantation by a Medicare approved heart transplant center and active on the wait list maintained by the Organ Procurement and Transplantation Network (OPTN), **OR**
2. 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**
3. Is in 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: (4 – 7)

4. VAD is determined to be necessary for sustaining life until a suitable donor heart is available, **AND**
5. Device planned for implantation is FDA approved for this indication and age-appropriate for the recipient, and the device intended is identified in the documentation provided, **AND**
6. Device is to be surgically implanted at a center approved by Medicare to perform these procedure, **AND**
7. If the center implanting the device is different from the Medicare Approved Transplant Center under which the patient is listed, the implanting center must secure written permission from the listing transplant center and that document must be included in the prior authorization application.

B. Initial Placement, LVAD, (Destination Therapy)

ALL of the following: (1 - 8)

1. Member must have completed workup to determine that member is NOT a candidate for heart transplantation, **AND**
2. Workup has determined that mechanical support is required to support life, **AND**
3. Must meet the specified clinical criteria of services provided at an FDA approved facility, **AND**
4. Must meet the NYHA Class IV end-stage ventricular heart failure criteria, **AND**
5. Have 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**
6. Must have a left ventricular ejection fraction (LVEF) of < 25%, **AND**
7. Must have demonstrated functional limitation with a peak oxygen consumption (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**
8. Device planned for implantation is FDA approved for this indication and age-appropriate for the recipient, and the device intended is identified in the documentation provided.

C. Initial Placement, VAD, (Temporary Indications) (Must meet either 1 or 2; and 3)

ONE of the following: (1 or 2)

1. Member is immediate post-cardiotomy, removal from cardiopulmonary bypass (CPB) is unsuccessful, and member is expected to recover to wean from VAD and CPB within the standard time requirements for VAD use, **OR**
2. Member is diagnosed with an acute cardiac failure for which temporary use of VAD is expected to allow recovery from VAD support within the usual time restrictions for VAD usage,

AND, the following:

3. Device planned for implantation is FDA approved for this indication and age appropriate for the recipient, and the device intended is identified in the documentation provided.

D. Initial Placement, Percutaneous VAD (pVAD), (Temporary Indications) (Must meet either 1 or 2; and 3)

ONE of the following, (1 or 2):

1. Acute cardiogenic shock from LVAD implantation, MI, heart transplant, open heart surgery, or similar circumstance, **OR**
2. As an adjunct to percutaneous coronary intervention (PCI) in high-risk patients undergoing unprotected left main or last –remaining-conduit PCI with ejection fraction less than 35% or with three vessel disease and ejection fraction less than 30%

AND, the following:

3. Recovery is anticipated such that the pVAD is not anticipated to be used more than 14 days.

E. Replacement, LVAD:

Replacement is covered if the above criteria were met at the time of implantation.

Note: Additional information may be required after initial review.

References:

1. Blue Cross Blue Shield Medical Coverage Guidelines, 10/11/2016.
2. OHCA; Policies & Rules, OAC 317: 30-3-1; 317:30-3-65.5; 317:30-5, Part 17.
3. Aetna Clinical Policy Bulletin: Ventricular Assist Devices, # 0654, 3/16/2017.
4. Priority Health, Medical Policy # 91509-R7, 2015.
5. United Health Care Guideline, Artificial Hearts and Related Devices, 2016.
6. NCD for Artificial Hearts and Related Devices (20.9).