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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Total Artificial Heart (TAH):

Syncardia Temporary TAH:
Previously known as the CardioWest™ TAH. The Syncardia™ Temporary TAH is a pulsating biventricular device that pumps blood to both the pulmonary and systemic circulation. It is implanted into the chest after the native ventricles are excised. This device may be used as a bridge to transplant in cardiac transplant-eligible individuals at risk of imminent death from biventricular failure. It is intended for use in the hospital setting.

AbioCor® Implantable Replacement Heart System:
A pulsatile, electrohydraulic device for implantation in individuals with advanced heart failure that involves both pumping chambers of the heart. The natural heart is removed during the procedure. The AbioCor Replacement Heart has been investigated as treatment for individuals with severe biventricular end-stage heart disease who are not eligible for a heart transplant and who are younger than 75 years of age, require multiple inotropic support, are not treatable by left ventricular assist devices (LVAD) destination therapy and are not weanable from biventricular support if on such support.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description: (cont.)

Ventricular Assist Device (VAD):
VAD is a mechanical pump that provides temporary or permanent circulatory support to a weakened heart. VAD may be used as a bridge to transplant when survival to transplantation is not expected, as permanent destination therapy when an individual with end-stage heart failure is not eligible for heart transplantation or to support circulation following open-heart surgery. VAD consists of a pump, a control system and an energy supply (battery or pneumatic). The energy supply and control system are located outside the body; the pump can be either inside or outside the body. Left VAD (LVAD) receives blood from the left ventricle and delivers it to the aorta. Right VAD (RVAD) receives blood from the right ventricle and delivers it to the pulmonary artery. Biventricular VAD (BVAD) supports both pulmonary and systemic circulation.

VADs with U.S. Food and Drug Administration (FDA) approval include:
- Thoratec® HeartMate II® LVAS
- Thoratec Implantable VAD (IVAD) manufactured and distributed after October 22, 2007. The FDA recalled Thoratec IVAD, Catalog Number 10012-2555-001, serial numbers 488 or higher manufactured and distributed from October 1, 2004 through October 22, 2007 (http://www.fda.gov/cdrh/recalls/recall-101907.html).

VADs with FDA approval under the Humanitarian Device Exemption (HDE) approval process include:
- CentriMag® Right Ventricular Assist Device (RVAD)
- DeBakey® VAD Child
- Berlin Heart® EXCOR® Pediatric VAD

Berlin Heart VADs without FDA approval include:
- Excor
- Incor®

Third Generation Continuous Flow Rotary Pump Ventricular Assist Device:
Third generation smaller LVAD continuous flow rotary pumps that have not yet received approval for marketing from the FDA include:
- DuraHeart™
- Levacor™
- VentrAssist™

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Description: (cont.)

Percutaneous Ventricular Assist Device (pVAD):
Percutaneous ventricular assist devices have been investigated for short-term use (6 hours or less) in individuals who require acute circulatory support. These devices consist of a catheter placed through the femoral artery and operate in one of the following ways:

- The catheter is passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system by way of the femoral artery
- A small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta

pVADs include, *but are not limited to:*

- Impella® Recover® LP 2.5 Percutaneous Cardiac Support System
- TandemHeart® Transseptal Cannula Set-EF

Criteria:

A. Ventricular Assist Devices as Temporary Therapy for Adults:

- Ventricular assist devices with FDA approval are considered ***medically necessary*** as temporary therapy with documentation of **ANY** of the following:

  1. Currently listed as a candidate for heart transplantation **or** are undergoing evaluation to determine candidacy and the VAD will be a temporary alternative to human heart transplantation until a human heart donor is available
  2. Post-cardiotomy and unable to be weaned off cardiopulmonary bypass

- CentriMag right ventricular assist device is considered ***eligible for coverage*** based upon its Humanitarian Device Exemption issued by the Food and Drug Administration and is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Intended to provide temporary circulatory support for up to 14 days
  2. Individual is in cardiogenic shock due to acute right ventricular failure

- Replacement of a ventricular assist device for temporary therapy is considered ***medically necessary*** if above criteria are met.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

A. Ventricular Assist Devices as Temporary Therapy for Adults: (cont.)

- Ventricular assist devices that lack final approval from the Food and Drug Administration for temporary therapy or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

B. Ventricular Assist Devices as Destination Therapy for Adults:

- Ventricular assist devices with FDA approval are considered ***medically necessary*** as destination therapy with documentation of **ALL** of the following:

  1. Ineligible for human heart transplantation due to **ANY** of the following:

     - Age > 65 years
     - Insulin dependent diabetes mellitus with end organ damage
     - Chronic renal failure (serum creatinine > 2.5 mg/dl for ≥ 90 days)
     - Presence of other clinically significant condition (e.g., irreversible hepatic or respiratory failure)

  2. **ONE** of the following classifications of heart failure:

     - New York Heart Association (NYHA) class IV for 60 days or more
     - New York Heart Association (NYHA) class III or IV for 28 days and **ONE** of the following

       - Received 14 days or more support with an intra-aortic balloon pump, **or**
       - Dependent on IV inotropic agents, with 2 failed weaning attempts

  3. End stage heart failure with left ventricular ejection fraction of 25% or less

- Replacement of a ventricular assist device for temporary therapy is considered ***medically necessary*** if above criteria are met.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

B. Ventricular Assist Devices as Destination Therapy for Adults: (cont.)

- Ventricular assist devices that lack final approval from the Food and Drug Administration for destination therapy or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

C. Ventricular Assist Devices for Children:

- DeBakey VAD Child Left Ventricular Assist System is considered ***eligible for coverage*** based upon its Humanitarian Device Exemption issued by the Food and Drug Administration and is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. 5 to 16 years of age
  2. Currently listed as a candidate for heart transplantation **or** is undergoing evaluation to determine candidacy
  3. End stage heart failure
  4. Body surface area (BSA) of greater than or equal to 0.7 m^2 and less than 1.5 m^2
  5. New York Heart Association (NYHA) class IV heart failure
  6. Heart failure is refractory to medical therapy

- Implantable ventricular assist devices with FDA approval, i.e, the Berlin Heart EXCOR Pediatric VAD device, including humanitarian device exemptions, are considered ***medically necessary*** as a bridge to heart transplantation with documentation of **ANY** of the following:

  1. 16 years or younger
  2. Currently listed as heart transplantation candidate and not expected to survive until a donor heart can be obtained **OR** are undergoing evaluation to determine candidacy for heart transplantation

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

C. Ventricular Assist Devices for Children: (cont.)

- Replacement of implantable ventricular assist devices with FDA approval, including humanitarian device exemptions, are considered ***medically necessary*** if above criteria are met.

- Ventricular assist devices that lack final approval from the Food and Drug Administration for use in children or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

D. Percutaneous Ventricular Assist Devices (pVADs):

- Percutaneous ventricular assist devices are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

E. Other Ventricular Assist Devices:

- The following ventricular assist devices are considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

  These devices include, *but are not limited to:*

  - Berlin Heart Excor
  - Berlin Heart Incor
  - DuraHeart
  - Levacor
  - VentrAssist

F. Total Artificial Heart:

- Total artificial heart devices with FDA approval as a bridge to transplantation are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Biventricular failure who have no other reasonable medical or surgical options
  2. Ineligible for other univentricular or biventricular support devices
  3. Currently listed as a candidate for heart transplantation **or** are undergoing evaluation to determine candidacy for heart transplantation and not expected to survive until a donor heart can be obtained.

- Total artificial heart devices as destination therapy are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Criteria: (cont.)

F. Total Artificial Heart: (cont.)

- Total artificial heart devices that lack final approval from the Food and Drug Administration or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. HeartWare® Ventricular Assist System Product Information. 2010 2010.

2. 7.03.11 BCBS Association Medical Policy Reference Manual. Total Artificial Hearts and Implantable Ventricular Assist Devices. Re-issue date 05/22/2014, issue date 11/30/1996.

3. Alasnag MA, Gardi DO, Elder M, et al. Use of the Impella 2.5 for prophylactic circulatory support during elective high-risk percutaneous coronary intervention. *Cardiovasc Revasc Med.* Sep-Oct 2011;12(5):299-303.

4. Burzotta F, Paloscia L, Trani C, et al. Feasibility and long-term safety of elective Impella-assisted high-risk percutaneous coronary intervention: a pilot two-centre study. *J Cardiovasc Med (Hagerstown).* Oct 2008;9(10):1004-1010.

5. Centers for Medicare & Medicaid Services. National Coverage Decision for Artificial Hearts and Related Devices. 03/27/2007 (Version 3).

6. Centers for Medicare & Medicaid Services. Ventricular Assist Devices as Destination Therapy (VAD). *Coverage Decision Memorandum.* 11/09/2010 2010.

7. Cohen MG, Ghatak A, Kleiman NS, et al. Optimizing rotational atherectomy in high-risk percutaneous coronary interventions: Insights from the PROTECT IotaIota study. *Catheter Cardiovasc Interv.* Oct 30 2013.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

8. Engstrom AE, Sjauw KD, Baan J, et al. Long-term safety and sustained left ventricular recovery: long-term results of percutaneous left ventricular support with Impella LP2.5 in ST-elevation myocardial infarction. *EuroIntervention.* Feb 2011;6(7):860-865.

9. FDA. Excor® Pediatric Ventricular Assist Device (VAD). *OOPD Grant of the Month.* Accessed 12/15/2010.

10. FDA. Berlin EXCOR® Pediatric Ventricular Assist Device (VAD) Humanitarian Device Exemption. 2011.

11. FDA. HeartWare Ventricular Assist System. 2012.

12. InterQual® Care Planning, Procedures. Left Ventricular Assist Device (LVAD) Insertion.

13. Kovacic JC, Nguyen HT, Karajgikar R, Sharma SK, Kini AS. The Impella Recover 2.5 and TandemHeart ventricular assist devices are safe and associated with equivalent clinical outcomes in patients undergoing high-risk percutaneous coronary intervention. *Catheter Cardiovasc Interv.* Jul 1 2013;82(1):E28-37.

14. Lauten A, Engstrom AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. *Circ Heart Fail.* Jan 2013;6(1):23-30.

15. Lemaire A, Anderson MB, Prendergast T, et al. Outcome of the impella device for acute mechanical circulatory support. *Innovations (Phila).* Jan-Feb 2013;8(1):12-16.

16. Martinez CA, Singh V, Londono JC, et al. Percutaneous retrograde left ventricular assist support for interventions in patients with aortic stenosis and left ventricular dysfunction. *Catheter Cardiovasc Interv.* Dec 1 2012;80(7):1201-1209.

17. Miller MA, Dukkipati SR, Chinitz JS, et al. Percutaneous hemodynamic support with Impella 2.5 during scar-related ventricular tachycardia ablation (PERMIT 1). *Circ Arrhythm Electrophysiol.* Feb 2013;6(1):151-159.

18. Miller MA, Dukkipati SR, Mittnacht AJ, et al. Activation and entrainment mapping of hemodynamically unstable ventricular tachycardia using a percutaneous left ventricular assist device. *J Am Coll Cardiol.* Sep 20 2011;58(13):1363-1371.

19. Pagani FD. Continuous-Flow Rotary Left Ventricular Assist Devices with "3rd Generation" Design. *Seminars in thoracic and cardiovascular surgery.* 2008/09/23 2008;20(3):255-263.

20. Slaughter MS, Ising MS, Tamez D, et al. Increase in circadian variation after continuous-flow ventricular assist device implantation. *J Heart Lung Transplant.* 2010 Jun 2010;29(6):695-697.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

21. Tuzun E, Roberts K, Cohn WE, et al. In vivo evaluation of the HeartWare centrifugal ventricular assist device. *Tex Heart Inst J.* 2007 2007;34(4):406-411.

22. Wood C, Maiorana A, Larbalestier R, Lovett M, Green G, O'Driscoll G. First successful bridge to myocardial recovery with a HeartWare HVAD. *J Heart Lung Transplant.* 2008 Jun 2008;27(6):695-697.

FDA Premarket Approval Database for Thoratec HeartMate II Left Ventricular Assist System LVAS:

- FDA-approved indication: For use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. It is also indicated for use in patients with New York Heart Association (NYHA) class IIIb or IV end stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and are not candidates for cardiac transplantation. The Heartmate II LVAS is intended for use both inside and outside the hospital, or for transportation of ventricular assist device patients via ground ambulance, fixed-wing aircraft, or helicopter.

FDA Humanitarian Device Exemption (HDE) for Debakey VAD Child LVAS:

- The HDE allows MicroMed: Technology, Inc. to market the above device for providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with body surface area of ≥ 0.7 m2 and < 1.5 m2) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are listed as candidates for cardiac transplantation.

FDA Humanitarian Device Exemption (HDE) for Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD):

- The device in intended to provide mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients. Pediatric candidates with severe isolated **left** ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

FDA Humanitarian Device Exemption (HDE) for CentriMag Right Ventricular Assist System (RVAS):

- FDA-approved indication: This device is intended to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure.

FDA Premarket Approval Database for Thoratec Implantable Ventricular Assist Device:

- FDA-approved indication: Bridge to cardiac transplantation for use in patients suffering from end-stage heart failure. The patient should meet all of the following criteria: 1) candidate for cardiac transplantation, 2) imminent risk of dying before donor heart procurement, and 3) dependence on, or incomplete response to, continue vasopressor support. Also indicated for post-cardiotomy patients who are unable to be weaned from cardiopulmonary bypass.

FDA Premarket Approval Database for Syncardia Temporary CardioWest Total Artificial Heart:

- FDA-approved indication: For use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. It is intended for use inside the hospital.

FDA Humanitarian Device Exemption (HDE) for AbioCor Replacement Heart:

- FDA-approved indication: For use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who are less than 75 years old, require multiple inotropic support, are not treatable by LVAD destination therapy and are not weanable from biventricular support if on such support.

FDA 510K Summary for Impella Recover LP 2.5 Percutaneous Cardiac Support System:

- FDA-approved indication: For partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

VENTRICULAR ASSIST DEVICES AND TOTAL ARTIFICIAL HEARTS (cont.)

Resources: (cont.)

FDA 510K Summary for TandemHeart Transseptal Cannula Set-EF:

- FD7A-approved indication: For transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the TandemHeart extracorporeal blood pump which returns blood to the patient via the femoral artery or other appropriate site.