I. Policy: Ventricular Assist Device (VAD)

II. Purpose/Objective:
To provide a policy of coverage regarding Ventricular Assist Device (VAD).

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member’s condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member’s Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member’s condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Ventricular assist device (VAD) is a mechanical pump that provides circulatory support for patients whose heart can no longer pump blood effectively due to heart failure. VAD’s are used temporarily in patients awaiting a heart transplant when their hearts are so severely damaged that the risk of death is imminent and in patients following open heart surgery with severe, but anticipated reversible dysfunction. VAD’s are also used as destination therapy in patients with end-stage heart failure without the intention of eventual heart transplantation.

INDICATIONS:
Ventricular assist devices that are FDA approved as medically necessary for the following indications when implanted postcardiotomy in an approved facility*:

- acute cardiogenic shock
- acute myocarditis
- individuals who are unable to be weaned from cardiopulmonary bypass following cardiac surgery
- Bridge-to-transplant when the risk of death is imminent from left ventricular heart failure
- Destination therapy when heart transplantation is not an option and when all of the following criteria are met:
  - New York Heart Association (NYHA)* class IV end-stage left ventricular heart failure for at least 90 days and life expectancy of less than 2 years; and
  - Class IV heart failure symptoms have failed to respond to optimal medical management (dietary salt restrictions, diuretics, digitalis, beta-blockers, and ACE inhibitors)
    - HeartMate XVE-LVAS patient has failed the optimal medical therapy for at least 60 of the last 90 days; or
    - HeartMate II patient has failed the optimal medical therapy for 45 of the last 60 days or dependence on an intra-aortic balloon pump for 7 days; and
  - Left ventricular ejection fraction (LVEF) is less than 25%; and
    - Demonstrated functional limitations with a peak oxygen consumption of <14ml/kg/min; or
    - The patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion;

Pediatric Patients:
Ventricular assist devices for pediatric patients are medically necessary for post-cardiotomy, when used according to the FDA approved labeling instructions for:

1. Support of blood circulation in the period following open heart surgery, or
2. Bridge-to-transplant when the following criteria are met:
   a. HeartAssist 5 VAD (DeBakey VAD child) when all of the following criteria are met:
      i. Between the ages of 5-16
      ii. NYHA Class IV end-stage heart failure
      iii. Listed as a candidate for heart transplant
      iv. Body Surface area is > 0.7 m² and < 1.5 m²
      OR;
   b. Berlin Heart EXCOR Pediatric VAD when all of the following criteria are met:
      i. Between the ages of 0-16
      ii. NYHA Class IV end-stage heart failure
      iii. Listed as a candidate for heart transplant

Note: The New York Heart Association functional classification system, below, is the most frequently used measure of heart failure and is included in the FDA approval criteria for most VADs.

- Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
• Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

FACILITY CRITERIA FOR DESTINATION VAD THERAPY:
• Facilities must have
  o at least one member of the VAD team with experience implanting at least 10 VADs (as bridge to transplant or destination therapy) or artificial hearts over the course of the previous 36 months;
  o At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
  o A VAD program coordinator.
  o A social worker.
  o A palliative care specialist
• Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services

*Note- All approved facilities are found on the CMS website at: https://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp

The Plan considers a FDA-approved percutaneous left ventricular assist device (LVAD) (e.g., the TandemHeart and the Impella Recover LP 2.5) medically necessary for providing short-term circulatory support in cardiogenic shock.

LIMITATIONS: Replacements of the device or a component of the device is considered medically necessary when any of the following criteria are met:

1. A change in the physiological condition of the insured individual documented in the medical record necessitates a different device; or

2. A comorbidity is proven to be exacerbated by the current device or component; or

3. A non-warranty repair of the device or component is imminent; and
   The cost of the required repair is estimated to be more than the cost of a replacement device or component.

EXCLUSIONS:
Replacement of an otherwise functioning device or its components for the sole purpose of upgrading to a newer model is not medically necessary and therefore, NOT COVERED

The Plan does NOT provide coverage for Ventricular Assist Devices for Artificial heart or any other indication that is not listed in the policy because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Ventricular Assist Device (VAD)

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.

33975  Insertion of ventricular assist device; extracorporeal, single ventricle
33976  Insertion of ventricular assist device; extracorporeal, biventricular
33977  Removal of ventricular assist device; extracorporeal, single ventricle
33978  Removal of ventricular assist device; extracorporeal, biventricular
33979  Insertion of ventricular assist device, implantable, intracorporeal, single ventricle
33980  Removal of ventricular assist device, implantable intracorporeal, single ventricle
33981 Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982 Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983 Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33990 Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991 Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33992 Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993 Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
CMS Decision Memo LVAD. Decision Memo for Ventricular Assist Devices as Destination Therapy (CAG-00119N). October 1, 2003

http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp


This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/24/12
Revised: 10/12, 5/13 (added coverage), 12/14 (added Limitations/Exclusion), 1/16 (added CMS facility criteria), 5/16 (Removed PA)

Reviewed: 6/14, 1/17