Policy: Ventricular assist devices (VAD’s), including Left Ventricular Assist Devices (LVAD’s) are used to sustain patients awaiting heart transplantation and to facilitate cardiac recovery in patients suffering from reversible cardiac dysfunction.

Procedure: Coverage Policy

Ventricular assist devices, including Left Ventricular Assist Devices, are considered for coverage through Meridian Health Plan (PM) in the following circumstances:

1. As a bridge to transplantation for patients who meet all of the following criteria:
   a. Is approved and listed for heart transplant.
   b. Has irreversible, terminal heart disease
   c. Has heart disease that is not amenable to other medical intervention or surgical procedure that would confer an equal survival advantage to heart transplantation
   d. Symptoms of advanced heart failure consistent with NYHA class IV limitations despite optimal medical management, requiring the initiation of inotropic therapy and / or intra-aortic balloon pump for:
      i. Hemodynamic instability (left atrial pressure or pulmonary capillary wedge pressure >20 mmHg with either
         1. SBP <80 mmHg or cardiac index <2.0L/min/m2, or

1 See Special instructions for additional Medicare/Medicaid Coverage
2. Heart rate > 120 beats/min
   OR
ii. Evidence of progressive organ dysfunction despite stable hemodynamic measurements;
   OR
iii. Life-threatening ventricular arrhythmias with contraindications to inotrope therapy

2. For short-term use (generally less than 2 weeks) in patients who present with cardiogenic shock with hemodynamic instability (left atrial pressure or pulmonary capillary wedge pressure > 20 mmHg with either
   a. SBP < 80 mmHg or cardiac index < 2.0L/min/m2 or
   b. heart rate > 120 beats/min despite optimal medical management including the use of inotrope therapy and an intra-aortic balloon pump when there is a likelihood of myocardial recovery.

3. Pediatric patients; The Heart Assist 5 Pediatric VAD (formerly the DeBakey VAD Child®) is covered as medically necessary as a bridge to cardiac transplantation in children when used in accordance with the FDA’s Humanitarian Device Exemption (HDE) requirements when ALL of the following criteria are met:
   a. age 5–16
   b. body surface area (BSA) ≥ 0.7 m2 and < 1.5 m2
   c. in NYHA Class IV end-stage heart failure
   d. refractory to medical therapy
   e. listed candidate for cardiac transplantation
   f. None of the following contraindications
      i. patients under age five or with BSA < 0.7 m2
      ii. patients suffering from right ventricular failure unresolved by medical therapy
      iii. patients with a primary coagulopathy or platelet disorders
      iv. prior surgery where apical cannulation, pump replacement or graft anastomosis is not feasible

Note: Current FDA-approved pediatric VADs include the Berlin Heart EXCOR Pediatric Ventricular Assist Device (for children aged 16 years or younger) and the HeartAssist 5 Pediatric Ventricular Assist Device-formerly the DeBakey VAD Child; MicroMed Technologies, Inc (for children aged 5 to 16 years).

4. All VADs must be implanted in a facility approved by Medicare to perform this procedure.

Facility Criteria (must meet all)
1. Facilities must have 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 mo.;
2. Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS); and,
3. By March 27, 2009, all facilities must meet the above facility criteria and be credentialed by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007).
4. VADs used as a bridge to transplantation, implanted at a site other than the Medicare-approved transplant center, must meet the following CMS criteria and language: “The implanting site, if different than the Medicare approved transplant center, must receive written permission from the Medicare approved heart transplant center under which the patient is listed prior to implementation of the VAD.”

Non-Coverage Policy

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2 See Special instructions for additional Medicare/Medicaid Non-Coverage
1. MHP does not cover percutaneous VADs (e.g., TandemHeart® PTVA® System, Impella Recover® LP 2.5 Percutaneous Cardiac Support System, Impella 5.0 Catheters) because they are considered experimental, investigational or unproven at this time.

2. Use of a non-FDA approved or cleared ventricular assist device, or an FDA approved device for a non-approved or off-label indication, is considered investigational.

3. A VAD is **not covered** if any of the following conditions are present, (non-covered conditions are not limited to this list):
   a. Irreversible multiple organ dysfunction
   b. Severely restricted pulmonary function
   c. Major neurological deficit
   d. Cerebral vascular accident with significant cognitive impairment
   e. Active, systemic infection
   f. Active malignancy, except for localized basal cell cancer
   g. Long-term high-dose corticosteroid use
   h. Presence of HIV infection
      i. Absence of HIV infection is defined by all of the following:
         1. CD4 count greater than 200 cells/mm$^3$ for more than 6 months; *and*
         2. HIV-1 RNA (viral load) undetectable; *and*
         3. On stable anti-viral therapy for more than 3 months; *and*
         4. No other complications from AIDS, such as opportunistic infection (e.g., aspergillus, coccidiomycosis, resistant fungal infections, tuberculosis), Kaposi’s sarcoma or other neoplasm.
   i. Blood clotting disorders
   j. Age >70 years
   k. Aortic aneurysm surgery
   l. Cardiogenic shock not related to cardiac surgery

**Special Instructions:**

**Medicaid/All:** A VAD for destination therapy is not a covered benefit

**Medicare/All:** Coverage Policy:

1. Postcardiotomy: VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions

2. Clinical Study: Artificial Hearts as a Bridge-to-Transplant is covered when performed under coverage with evidence development (CED) when a clinical study meets all of the criteria listed below:
   a. Study is reviewed and approved by the FDA
   b. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
   c. The research study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
   d. The research study does not unjustifiably duplicate existing studies.
   e. The research study design is appropriate to answer the research question being asked in the study.
   f. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

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3 (Ward, Slutsker, Buehler, Jaffe, Berkelman, & Curran, 1992)
g. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated it also must be in compliance with 21 CFR Parts 50 and 56.

h. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

i. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with study participation (CSP) or CED coverage.

j. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in health individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

k. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator as demonstrated by having a National Clinical Trial Control number.

l. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

m. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

n. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

o. Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the listed research questions below ((xvi)(5)(a-c)).

p. The principal investigator of an artificial heart clinical study seeking Medicare payment should submit the following documentation to the Centers for Medicare & Medicaid Services (CMS) and should expect to be notified when the CMS review is complete:
   1. Complete study protocol (must be dated or identified with a version number);
   2. Protocol summary;
   3. Statement that the submitted protocol version has been agreed upon by the FDA;
   4. Statement that the above study standards are met;
   5. Statement that the study addresses at least one of the questions related to artificial hearts;
      a. Were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes?
      b. What will be the average time to device failure when the device is made available to larger numbers of patients?
c. Do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more widespread use?

6. Complete contact information (phone number, email address, mailing address); and,

7. Clinicaltrials.gov registration number

3. VADs as Destination Therapy:
   a. For patients who require permanent mechanical cardiac support; or
   b. Have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) and who are not candidates for heart transplantation, must meet all of the following conditions:
      i. Failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
      ii. Have a left ventricular ejection fraction (LVEF) <25%, and, Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

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Approved by: ___________________________  Date: 10/20/2015
Corporate Chief Operating Officer

Reviewed and approved by Policy and Procedure Committee:  Date: 07/17/2015
Reviewed and approved by Medical Policy Operations Committee:  Date: 07/31/2015
Reviewed and approved by Physician Advisory Committee:  Date: 09/25/2015
Reviewed and approved by Corporate Compliance Committee:  Date: 10/20/2015

References:
5. FDA Information on the DeBakey VAD ® Child: [DeBakey VAD (R) Child- H030003](http://medicalexpress.us/DeBakey_VAD_Child_H030003/)
6. Hayes Inc; Medical technology Directory, Ventricular Assist Devices, May 2005

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20. Circulation.2014; 129: 1530-1537 Challenges and Opportunities in Pediatric Heart Failure and Transplantation Ventricular Assist Devices in Children Progress With an Orphan Device Application Christina J. VanderPluym, MD; Francis Fynn-Thompson, MD; Elizabeth D. Blume, MD

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