



VENTRICULAR ASSIST DEVICES & ARTIFICIAL HEARTS

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Status: Current

Summary of Changes

Clarifications:

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Deletions:

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Additions:

- Pg 2, Section I, A 3, c, criteria updated to include additional measures from CPXT that would demonstrate poor short and intermediate term survival.
- Pg 2, Section I, A, 3, d, criteria added to reflect CPXT results (criteria #3c) may be waived for those patients who are inotrope dependent and were too ill to perform CPXT prior to initiation of inotropes.
- Pg 2, Section I, A, 5, language added to reflect the use of LVAD for a long term bridge to recovery is not considered standard therapy.

I. POLICY/CRITERIA

VADs:

A. Use of an FDA-approved ventricular assist device (VAD) is considered medically necessary when used as labeled and for an FDA-approved indication listed below:

1. As a **bridge to transplantation** for patients who meet *all* of the following criteria:
 - a. Is an approved heart transplant candidate or is a potential heart transplant candidate who has a relative contraindication(s) to heart transplantation in which there is a reasonable assurance that the contraindication can be favorably modified by the use of ventricular assist device therapy (i.e. renal dysfunction, elevated pulmonary vascular resistance, debilitation and cardiac cachexia).
 - b. Has heart disease that is not amenable to another surgical procedure that would confer an equal survival advantage to heart transplantation.
 - c. Has symptoms of advanced heart failure consistent with NYHA class IV limitations despite optimal medical management and requiring the initiation of inotrope therapy and / or intra-aortic balloon pump.
2. For **short-term use** (generally less than 2 weeks), as a **bridge to decision for either of the following:**



- a. patients who present with cardiogenic shock with hemodynamic instability despite optimal medical management including the use of inotrope therapy and intra-aortic balloon pump when there is a likelihood of myocardial recovery, OR
 - b. post-cardiotomy surgery patients who cannot be weaned from cardiopulmonary bypass.
3. As **destination therapy** in patients meeting *all* of the following criteria:
- a. End-stage heart failure.
 - b. Documented ineligibility for human heart transplantation.
 - c. Cardiopulmonary stress test (CPXT) with a peak oxygen consumption (i.e. peak VO₂) less than or equal to 14ml/kg or a similar validated measure (e.g. predicted VO₂, lean adjusted VO₂, VE/VCO₂ slope) demonstrating poor short and intermediate term survival AND one of the following:
 - NYHA class III or IV* for at least 28 days who have received at least 14 days support with an intra-aortic balloon pump or are dependent on IV inotropic agents, with two failed weaning attempts, *or*
 - New York Heart Association (NYHA) class IV* heart failure for at least 60 days
 - d. CPXT results (criteria #3c) may be waived for those patients who are inotrope dependent and were too ill to perform CPXT prior to initiation of inotropes.
- *NYHA Class III = marked limitation of physical activity; less than ordinary activity leads to symptoms
- *NYHA Class IV = inability to carry on any activity without symptoms; symptoms may be present at rest
4. For use to provide temporary left sided mechanical circulatory support as a bridge to cardiac transplantation **for pediatric patients** who meet all the following criteria:
- a. NYHA Class IV end-stage heart failure
 - b. Refractory to medical therapy and who are listed candidates for cardiac transplantation
5. There is growing experience that many patients experience improvements in myocardial function over time after left ventricular assist device implantation and ongoing treatment with cardiac reverse remodeling medications. This can at times be of sufficient extent to allow removal of their LVAD (long term bridge to recovery). At the present time, the likelihood of such LVAD bridge to recovery is low enough that placement



of an LVAD for the expressed purpose of myocardial recovery alone is not considered standard therapy. Patients should meet criteria for LVAD implantation for one of the above indications, although there is recognition that ongoing treatment with cardiac reverse remodeling medications and periodic surveillance for myocardial recovery is advisable. At times transplantation may be delayed for a period of time to observe for myocardial recovery. Other patients who have been implanted as a destination LVAD may be able to be weaned from LVAD support.

6. VADs are often implanted emergently and without obtaining prior Plan authorization. Plan notification is required, even after implantation, since these members require case management.
- B. All VADs must be implanted in a facility approved by Medicare to perform this procedure. VADs used as a bridge to transplantation, implanted at a site other than the Medicare-approved transplant center, must meet the following CMS 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.
- C. Use of a non-FDA approved ventricular assist device is considered investigational.
- D. A VAD is not covered if any of the following conditions are present, non-covered conditions are not limited to this list:
1. Irreversible multiple organ dysfunction
 2. Severely restricted pulmonary function
 3. Major neurological deficit
 4. Cerebral vascular accident with significant cognitive impairment
 5. Active, systemic infection
 6. Active malignancy, except for localized basal cell cancer
 7. Long-term high-dose corticosteroid use
 8. HIV seropositivity
 9. Blood clotting disorders
 10. Age \geq 80 years

Artificial Hearts:

Bridge to Transplant: An FDA-approved total artificial heart (e.g., CardioWest Total Artificial Heart), is a covered benefit when used as a bridge to transplant for transplant-eligible members who are at imminent risk of death (NYHA Class IV) due to biventricular failure who are awaiting heart transplantation.



Destination Therapy: Use of a total artificial heart as a permanent treatment (i.e. as an alternative to heart transplantation) may be a covered benefit in accordance with the FDA’s Humanitarian Device Exemption if implanted in a clinical study that meets the CMS study requirements (CMS approved clinical studies are listed @ http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp)

Members receiving VADs or Artificial Hearts (pre or post-op) must have an advanced care planning assessment (see Appendix A at the end of this medical policy) completed by a qualified provider. The assessment should accompany the request for a VAD or artificial heart.

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID:** *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule, the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html will govern.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*



IV. DESCRIPTION

Ventricular assist devices (VADs) and total artificial hearts (TAH) may be used to sustain patients awaiting heart transplantation, to facilitate cardiac recovery in patients suffering from reversible cardiac dysfunction, and to provide permanent circulatory support in patients with end-stage heart failure (HF) who are not candidates for transplantation.

Ventricular assist devices (VADs) are used to assist the left ventricle (LVADs), the right ventricle (RVADs), or both, and removal of the native heart is not necessary; VADs do not replace the heart, but rather work with the patient's own heart to pump sufficient blood throughout the body, and, thus, are used as auxiliary or parallel pumps. The VAD consists of a pump, a control system, and an energy supply.

There is substantial evidence that LVADs can provide effective circulatory support for patients with end-stage HF, and that the improved hemodynamics that these devices provide can help to stabilize and possibly reverse damage to myocardial tissue and secondary organs in patients waiting for transplantation, improving survival both before and after transplantation. There also is evidence to support the use of LVADs as intermediate-term support for HF patients who may subsequently recover sufficient function of the native heart to allow explantation. In addition, there is recent evidence to support the use of LVADs as permanent, or destination, therapy for end-stage HF patients who are not suitable candidates for transplantation.

A total artificial heart (TAH) is an implantable, pneumatic, biventricular support device that serves as a total replacement for both ventricles of the failing heart. Historically, the objective of implanting a TAH has been as a temporary measure to improve the likelihood of survival before and after heart transplantation in patients with end-stage heart failure (HF) who meet standard, accepted criteria for heart transplantation, who are at imminent risk of death and have no other treatment options, and for whom a compatible donor heart is unavailable. More recently, a TAH has been developed for use as destination therapy (permanent use) in patients with severe, irreversible biventricular HF who are not candidates for other therapies, including transplantation.

V. CODING INFORMATION

ICD9 Diagnosis Codes

These diagnoses may support medical necessity

- 402.00 – 402.90 Hypertensive heart disease
- 404.01 – 404.93 Hypertensive heart and chronic kidney disease
- 410.00 – 410.92 Acute myocardial infarction
- 425.0 – 425.9 Cardiomyopathy



428.0 – 428.9	Heart Failure
429.1	Myocardial degeneration
785.51	Cardiogenic shock
996.00	Mechanical complication of unspecified cardiac device, implant, and graft
996.09	Mechanical complication of other cardiac device, implant, and graft
997.1	Cardiac complications
V43.21	Heart assist device
V43.22	Fully implantable artificial heart
V45.00	Unspecified cardiac device, in situ
V45.81	Postprocedural aortocoronary bypass status
V49.83	Awaiting organ transplant status

CPT Codes:

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
93750	Interrogation of ventricular assist device (VAD), in person, with physician analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report (<i>no auth required</i>)
0048T	Implantation of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation
0050T	Removal of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation
0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)
0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart), excluding thoracic unit

HCPCS Codes - Replacement Device, Supplies & Components

(Device and all supplies for initial unit are included in the IP stay)

Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
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- Q0479 Power module for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0480 Driver for use with pneumatic ventricular assist device, replacement only
- Q0481 Microprocessor control unit for use with electric ventricular assist device, replacement only
- Q0482 Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only
- Q0483 Monitor/display module for use with electric ventricular assist device, replacement only
- Q0484 Monitor/display module for use with electric or electric/pneumatic ventricular assist device,-replacement only
- Q0485 Monitor control cable for use with electric ventricular assist device, replacement only
- Q0486 Monitor control cable for use with electric/pneumatic ventricular assist device, replacement-áonly
- Q0487 Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only
- Q0488 Power pack base for use with electric ventricular assist device, replacement only
- Q0489 Power pack base for use with electric/pneumatic ventricular assist device, replacement only
- Q0490 Emergency power source for use with electric ventricular assist device, replacement only
- Q0491 Emergency power source for use with electric/pneumatic ventricular assist device, replacement only
- Q0492 Emergency power supply cable for use with electric ventricular assist device, replacement only
- Q0493 Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only
- Q0494 Emergency hand pump for use with electric/pneumatic ventricular assist device, replacement only
- Q0495 Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device replacement only
- Q0496 Battery for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0497 Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0498 Holster for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0499 Belt/vest for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0500 Filters for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0501 Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only
- Q0502 Mobility cart for pneumatic ventricular assist device, replacement only
- Q0503 Battery for pneumatic ventricular assist device, replacement only, each
- Q0504 Power adapter for pneumatic ventricular assist device, replacement only, vehicle type



- Q0505 Miscellaneous supply or accessory for use with ventricular assist device
Q0506 Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

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CMS NCD for Artificial Hearts & Related Devices @

http://www.cms.hhs.gov/MCD/viewncd.asp?ncd_id=20.9&ncd_version=4&basket=ncd%3A20%2E9%3A4%3AArtificial+Hearts+and+Related+Devices (Retrieved October 1, 2009)

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APPENDIX A

ADVANCED CARE PLANNING ASSESSMENT

Medical history and reason for referral:

Current mental status:

Patient's description of current physical/mental symptoms and rating of overall quality of life:

Current level of functioning (compared to baseline):

Description of patient's family/social support system and their involvement in patient's care and decision making:

Status of patient's advanced directives:

Status of patient's designation of durable power of attorney:

Patient's understanding of current disease status and overall prognosis:

Spiritual beliefs related to illness and death:

Patient's wishes/goals for remainder of life (quality of life vs. length of life; importance of physical comfort; how patient wishes to spend time, etc):

Medical care options discussed with patient:

Patient's preference, if stated, for medical care:

Family members' preferences, if stated, for patient's medical care