Priority Health

MEDICAL POLICY
No. 91509-R12

VENTRICULAR ASSIST DEVICES & ARTIFICIAL HEARTS

Effective Date: August 1, 2025

Review Dates: 8/05, 6/06, 6/07, 6/08, 10/08, 10/09, 10/10, 10/11, 10/12, 10/13, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19, 11/20, 2/21, 2/22, 2/23, 2/24, 2/25, 5/25

Date Of Origin: August 10, 2005

Status: Current

Summary of Changes

Additions:

- I. Ventricular Assist Devices (VADs):

  Vitals monitoring: Real-time at-home or remote monitoring of vitals (e.g., INR, blood pressure, weight, temperature, oxygen saturation) through Bluetooth or similarly enabled or enhanced meters, blood pressure cuffs, scales, thermometers, pulse oximeters, or similar devices is considered not medically necessary—such enhancements are for convenience. Priority Health will not reimburse for any additional costs associated with such enhancements over more conventional instruments not so equipped. These include, but are not limited to, the following:

  INRTrac (ODI; Orthodynamics Company, Inc.): Bluetooth-enabled INR meter, blood pressure cuff, scale, thermometer, and pulse oximeter connect to a wireless hub. Incorporates an online portal for sharing biometric data with provider.

I. POLICY/CRITERIA

Ventricular Assist Devices (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.

Requests for authorization should be submitted on the Solid Organ Transplant prior authorization form.

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 VO_2) 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

   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 both of 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.

7. Percutaneous left ventricular assist devices (e.g., the TandemHeart and the Impella) are considered medically necessary for FDA-approved indications. Percutaneous LVADs are considered experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

8. Percutaneous right ventricular assist devices (RVADs): The Impella RP System and Impella 5.5 with SmartAssist is considered medically necessary for up to 14 days in a child or adult with a BSA ≥ 1.5 m^2 for the treatment of acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

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. **Vitals monitoring**: Real-time at-home or remote monitoring of vitals (e.g., INR, blood pressure, weight, temperature, oxygen saturation) through Bluetooth or similarly enabled or enhanced meters, blood pressure cuffs, scales, thermometers, pulse oximeters, or similar devices is considered not medically necessary—such enhancements are for convenience. Priority Health will not reimburse for any additional costs associated with such enhancements over more conventional instruments not so equipped. These include, but are not limited to, the following:

- INRTrac (ODI; Orthodynamics Company, Inc.): Bluetooth-enabled INR meter, blood pressure cuff, scale, thermometer, and pulse oximeter connect to a wireless hub. Incorporates an online portal for sharing biometric data with provider.

E. A VAD is considered not medically necessary if any of the following conditions are present (conditions for which a VAD is considered not medically necessary 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 considered medically necessary 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. Requests for authorization should be submitted on the Solid Organ Transplant prior authorization form.

Destination Therapy: Use of a total artificial heart as a permanent treatment (i.e. as an alternative to heart transplantation) may be considered medically necessary.

Coverage in a clinical trial is defined in the Priority Health Clinical Trials medical policy.

December 1, 2020: As per National Coverage Analysis (NCA) Decision Memo CAG-00453N, CMS has removed the NCD at § 20.9, ending coverage with evidence development for artificial hearts and permitting Medicare coverage determinations for artificial hearts to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act.

Members receiving VADs or Artificial Hearts (pre or post-op) must have an advance 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

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

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) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the***

Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify 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 explanation. 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

ICD-10 Codes that may support medical necessity:

I11.0 – I11.9	Hypertensive heart disease
I13.0 – I13.2	Hypertensive heart and chronic kidney disease
I21.01– I21. A9	Acute myocardial infarction
I22.0 – I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I23.0 – I23.8	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)
I42.0 – I42.9	Cardiomyopathy
I43	Cardiomyopathy in diseases classified elsewhere
I50.1 – I50.9	Heart failure
I51.5	Myocardial degeneration
I51.7	Cardiomegaly
I51.9	Heart disease, unspecified
I97.0	Postcardiotomy syndrome
I97.110 – I97.191	Other post procedural cardiac functional disturbances
I97.710 – I97.791	Intraoperative cardiac functional disturbances
I97.810 – I97.89	Other intraoperative and post procedural complications and disorders of the circulatory system, not elsewhere classified
R57.0	Cardiogenic shock
T82.221A - T82.228S	Mechanical complication of biological heart valve graft
T82.512A - T82.512S	Breakdown (mechanical) of artificial heart
T82.518A - T82.518S	Breakdown (mechanical) of other cardiac and vascular devices and implants
T82.519A - T82.519S	Breakdown (mechanical) of unspecified cardiac and vascular devices and implants
T82.522A – T82.522S	Displacement of artificial heart
T82.528A – T82.528S	Displacement of other cardiac and vascular devices and implants
T82.529A – T82.529S	Displacement of unspecified cardiac and vascular devices and implants
T82.532A - T82.532S	Leakage of artificial heart
T82.538A - T82.538A	Leakage of other cardiac and vascular devices and implants
T82.539A - T82.539S	Leakage of unspecified cardiac and vascular devices and implants
T82.592A - T82.592A	Other mechanical complication of artificial heart
T82.598A - T82.598S	Other mechanical complication of other cardiac and vascular devices and implants
T82.599A - T82.599S	Other mechanical complication of unspecified cardiac and vascular devices and implants
Z76.82	Awaiting organ transplant status
Z95.1	Presence of aortocoronary bypass graft
Z95.811	Presence of heart assist device
Z95.812	Presence of fully implantable artificial heart
Z95.9	Presence of cardiac and vascular implant and graft, unspecified

CPT Codes:

** No prior authorization required for removal or repositioning when performed as a separate service, or for interrogation services*

33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929*	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
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; left heart, both arterial and venous access, with transseptal puncture
33992*	Removal of percutaneous left ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993*	Repositioning of percutaneous right or left ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997*	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion
93750*	Interrogation of ventricular assist device (VAD), in person, with physician analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report

HCPCS Codes - Replacement Device, Supplies & Components - P*rior Authorization required for Q0508 when charges exceed $1,000, $500 for Medicaid; Device and all supplies for initial unit are included in the IP stay.*

L8698 Miscellaneous component, supply or accessory for use with total artificial heart system
Q0477 Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0478 Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
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
Q0506 Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0507 Miscellaneous supply or accessory for use with an external ventricular assist device
Q0508 Miscellaneous supply or accessory for use with an implanted ventricular assist device *(Prior Authorization required)*
Q0509 Miscellaneous supply or accessory for use any implanted ventricular assist device for which payment was not made under Medicare part A

Related procedures:
33967* Insertion of intra-aortic balloon assist device, percutaneous
33968* Removal of intra-aortic balloon assist device, percutaneous
33970* Insertion of intra-aortic balloon assist device through the femoral artery, open approach
33971* Removal of intra-aortic balloon assist device including repair of femoral artery, with or without graft
33973* Insertion of intra-aortic balloon assist device through the ascending aorta
33974* Removal of intra-aortic balloon assist device from the ascending aorta, including repair of the ascending aorta, with or without graft
92970* Cardioassist-method of circulatory assist; internal
92971* Cardioassist-method of circulatory assist; external

VI. REFERENCES

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APPENDIX A
ADVANCE CARE PLANNING ASSESSMENT

1. **Medical history and reason for referral:**

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

   Medical care options discussed with patient:

3. **Has patient completed an Advance Care Planning conversation, including designation of patient advocate as part of the advance directive, with a certified ACP facilitator*? Yes ☐ No ☐ If no, answer questions 4-9. If yes, this form is complete.**

4. **What are 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.)?**

5. **How does patient describe their current physical/mental symptoms? What is quality of life rating using QOL, HR QOL scale, SF 36 (short-form health questionnaire)?**

6. **Spiritual or cultural beliefs related to illness and death that would affect enrollment? Yes ☐ No ☐**

7. **Is advance directive complete? Yes ☐ No ☐**
   (i.e. Making Choices Michigan)

8. **Patient has designated a durable power of attorney for healthcare? Yes ☐ No ☐**

9. **Does family/patient advocate support patient's preference for medical care as outlined in advance directive? Yes ☐ No ☐**

***Certified ACP facilitators are trained through the Respecting Choices® curriculum. Trained facilitators are available at health systems, Making Choices Michigan, and community organizations.**