Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Ventricular Assist Devices

Policy Number: PG0070
Last Review: 02/01/2024

GUIDELINES:

- **This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.**
- **Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.**
- **This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.**

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Ventricular assist devices (VAD) are blood pumps that are designed to assist or replace the function of either the right or left ventricle of the heart. There are three kinds of ventricular assist devices: biventricular (BiVADs), right ventricular (RVADs), and left ventricular (LVADs). A right VAD supports the pulmonary (lung) circulation, while a left VAD (the most commonly used) provides blood flow to the rest of the body. Ventricular assist devices are utilized to promote cardiac health in those patients suffering from reversible cardiac dysfunction, to support patients who are awaiting heart transplantation or to provide permanent circulatory support in patients with end-stage heart failure who are not candidates for transplantation (known as destination therapy).

External implanted ventricular assist devices include the following types:

- A destination VAD: the placement of the device when no transplant is being considered
- A Bridge to Transplant VAD: the device is placed to support functioning in anticipation of a heart transplant.
- A Bridge to Decision VAD: The device is implanted to stabilize member and allow for determination of best long-term treatment option.
- Bridge to Recovery VAD: The device is placed with the goal of allowing heart muscle to recover, with the goal of eventual VAD removal.

The left VAD is a pump that is implanted into the patient's upper abdominal wall. It utilizes a tube that pulls blood from the left ventricle into the pump; it then sends blood (via another tube) back into the aorta, which then sends the oxygenated blood to the body. This bypasses the weakened pumping chamber of the heart. The patient is connected to an external power source via a tube extending from the body.

Many different VADs have been approved by the US Food and Drug Administration (FDA) including, but not limited to, the following:

- Bridge to transplant: Abiomed AB5000, HeartMate II, HeartMate II LVAS, HeartMate IP, HeartMate SNAP VE LVAS, HeartMate VE LVAS, HeartMate XVE LVAS, HeartWare VAS, Novacor LVAS, Thoratec IVAD, Thoratec VAD System
- Destination therapy: AbioMed BVS5000, HeartMate SNAP-VE LVAS, HeartMate XVE LVAS, HeartMate II
- Short-term bridge to recovery: AbioMed AB5000, AbioMed BVS5000, Thoratec IVAD, Thoratec VAD

System
- Pediatric bridge to transplant: HeartAssist 5 Pediatric VAD (formerly known as DeBakey VAD Child), EXCOR Pediatric VAD

Percutaneous ventricular assist device (pVAD) is another type of VAD that is available for short-term bridge to recovery, typically only 6 hours to 14 days. These devices are able to be placed via cardiac catheterization without the need for open-chest surgery. They also differ from other VADs in that they use a trans-septal approach to the left ventricle (the catheter is advanced across the intra-atrial septum into the left atrium), which avoids potential difficulties in crossing the aortic valve. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

Examples of pVADs include, but may not be limited to, the following:
- Impella Recover LP 2.5
- Impella 5.0 Percutaneous Cardiac Support System
- Impella CP (Cardiac Power)
- TandemHeart PTVA System

The Levitronix CentriMag Right Ventricular Assist System (RVAS) has received FDA approval for temporary use in those individuals who have cardiogenic shock due to right sided heart failure and need temporary circulatory support (up to 14 days).

The severity of heart failure is a key factor in assessing the need for VAD use. The New York Heart Association (NYHA) 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.

Permanently implantable aortic counter-pulsation ventricular assist devices have been proposed as a bridge to recovery for patients with acute or chronic heart failure. These devices employ a counter-pulsation device that is surgically implanted in the aorta, which inflates during diastole to reduce end diastolic ventricular pressure on a long-term basis without re-routing blood flow. Multiple devices are being investigated but presently no device has received FDA-approval. There are scarce data in the published, peer-reviewed scientific literature regarding the safety and effectiveness of implantable aortic counter-pulsation VADs in the treatment of heart failure.

Examples of devices in development or in clinical trials include, but may not be limited to, the following:
- CardioVAD (LVAD Technology, Detroit, MI)
- Symphony device (Abiomed Inc, Danvers, MA)
- C-Pulse device (Sunshine Heart Inc, Eden Prairie, MN)

Total artificial hearts (TAH) are biventricular devices, which completely replace the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the heart must be removed, failure of the device is synonymous with cardiac death.

Examples of TAH devices include, but may not be limited to, the following:

- SynCardia Temporary Total Artificial Heart (formerly CardioWest™ Temporary Total Artificial Heart): FDA approved for use inside the hospital as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure
- AbioCor® Implantable Replacement Heart System: FDA approved through the HDE process for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who:
  - Are younger than 75 years of age
  - Require multiple inotropic support
  - Are not treatable by left ventricular assist device (LVAD) destination therapy
  - Are not weanable from biventricular support if on such support
  - Have a chest volume large enough to hold the device as determined by a screening process

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Ventricular assist devices (33975-33983) do not require prior authorization.

Percutaneous ventricular assist devices (33990-33993, 33998, 33997) do not require prior authorization.

Total artificial hearts (TAH) (33927-33929) do not require prior authorization. Additionally, refer to medical policy PG0461 Transplant Prior Authorization and Notification.

Permanently implantable aortic counter-pulsation ventricular assist systems (0451T-0463T) are non-covered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

It is the policy of Paramount Healthcare that all FDA approved Ventricular Assist Devices, when used according to their FDA labeled indications (including body size recommendations), are considered medically necessary in the following situations:

Paramount Commercial Insurance Plans

Ventricular Assist Devices (VADs) including Left, Right and Biventricular Assist Devices (Adult)

FDA approved ventricular assist devices (VADs) are considered medically necessary as a *bridge to heart transplant* for individuals when ALL the following criteria have been met:

1. Have severe end stage heart failure
2. Are not expected to survive until a donor heart can be obtained
3. When one of the following criteria has been met:
   a. Currently listed as a heart transplant candidate
   b. Undergoing evaluation to determine candidacy for heart transplant

FDA approved VADs are considered medically necessary in the *post-cardiotomy setting* as a means of myocardial recovery support for individuals who are unable to be weaned off cardiopulmonary bypass.

FDA approved VADs are considered medically necessary when used as a *permanent alternative (destination therapy)* to heart transplantation for an individual when ALL the following criteria have been met:

1. Was evaluated and determined not to be eligible for a heart transplant for 1 or more of the following reasons:
   - Age >65 years; OR are not candidates for human heart transplant for 1 or more of the following reasons:
   - Insulin-dependent diabetes mellitus with end-organ damage; OR
   - Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days); OR
   - Presence of other clinically significant condition

2. The member has either of the following:
    a. New York Heart Association (NYHA) Class IV heart failure for ≥60 days; OR
    b. NYHA Class III/IV for 28 days, received ≥14 days' support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts
3. Has received optimal medical management, (i.e., oral, or intravenous medication, intra-aortic balloon pump, oxygen) for at least 60 of the last 90 days or the individual's survival is in jeopardy
4. Has a life expectancy of less than 2 years due to heart disease

Ventricular Assist Devices (Pediatric)

FDA approved pediatric VADs, including humanitarian device approvals are considered medically necessary for use in children when all the following criteria have been met:

1. Child has documented end-stage left ventricular failure
10. Are not expected to survive until a donor heart can be obtained
    - Requires mechanical circulatory support until a donor heart can be found
3. When one of the following criteria has been met:
    a. Currently listed as a heart transplant candidate
    b. Undergoing evaluation to determine candidacy for heart transplant

*Current FDA approved ventricular assist devices for children based on ages are:

a. Child under age 5: the Berlin Heart EXCOR® Pediatric Ventricular Assist Device
b. Child between ages 5 and 16: either the HeartAssist®5 Pediatric Ventricular Assist Device or the Berlin Heart EXCOR Pediatric Ventricular Assist Device

Not Medically Necessary:

Pediatric VADs are considered not medically necessary in children when all the criteria specified above are not met, or when any of the following contraindications are present:

1. Have right ventricular failure
2. Have a blood-clotting (primary coagulopathy) or platelet disorder such as hemophilia or Von Willebrand's disease
3. Have a known allergy or sensitivity to the blood thinner heparin
4. Have anatomical anomalies that would prevent surgical connection of the outflow graft to the ascending aorta

Elite (Medicare Advantage) Plans

Ventricular Assist Devices (VADs)

FDA approved VADs for short-term for example, bridge-to-recovery and bridge-to-transplant) or long-term (for example, destination therapy) mechanical circulatory support for heart failure patients meeting the following criteria:

1. Have New York Heart Association (NYHA) Class IV heart failure; and
2. Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
3. Are inotrope dependent OR have a Cardiac Index (CI) < 2.2 L/min/m2 while not on inotropes and meet 1 of the following:
    a. Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond
    b. Have advanced heart failure for at least 14 days and dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for least 7 days

FDA approved VADs are considered medically necessary in the *post-cardiotomy setting* as a means of myocardial recovery support for individuals who are unable to be weaned off cardiopulmonary bypass.

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Percutaneous Ventricular Assist Devices (pVADs)

Percutaneous ventricular assist devices (pVADs) (e.g., TandemHeart® or the Impella®) approved by the U.S. Food and Drug Administration (FDA) and used according to their FDA-approved specifications may be considered medically necessary when:

1. Providing short-term circulatory support in ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction; OR
2. As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk patients:
    a. Persons undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35 percent
    b. Persons with three vessel disease end ejection fraction less than 30 percent

Limitations for Implantable VADs

Contraindications, not all-inclusive:

1. Life expectancy in the absence of heart disease ≤ 2 years;
2. Malignancy within 5 years that is expected to significantly limit survival;
3. Irreversible multiple organ dysfunction;
4. Severely restricted pulmonary function;
5. Irreversible renal or hepatic dysfunction, severe obstructive pulmonary disease, or other systemic disease with multi-organ involvement;
6. A pattern of demonstrated noncompliance or lack of sufficient caregiver support which would place a VAD at serious risk of failure;
7. Major neurological deficit
8. Active, systemic infection
9. Blood clotting disorders
10. Active substance abuse, including alcohol.

Total Artificial Hearts

The use of an FDA-approved or cleared total artificial heart meets the definition of medical necessity as a bridge to transplantation when all the following are met:

- Biventricular failure with no other reasonable medical or surgical treatment options
- Ineligible for other univentricular or biventricular support devices
- Currently listed a heart transplant candidate or undergoing evaluation to determine candidacy for heart transplant
- Have no other reasonable medical or surgical treatment options
- Not expected to survive until a donor heart can be obtained

Investigational and Not Medically Necessary

- Ventricular assist devices are considered investigational and not medically necessary for all other conditions not listed above.
- Use of a non-FDA approved or cleared ventricular assist device is considered investigational and not medically necessary.
- Permanently implantable aortic counter pulsation VADs for any indication is non-covered because it considered experimental, investigational, or unproven.
- Other applications of total artificial hearts, including the use of total artificial hearts as destination therapy, are considered experimental or investigational. There is insufficient clinical evidence in the peer-reviewed literature to allow conclusions on health outcomes.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

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; left heart, 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 right or left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993	Repositioning of percutaneous right or left heart 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 or other qualified health care professional 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
0451T	Insertion or replacement of a permanently implantable aortic counter pulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counter pulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes) (Effective 01/01/17)
0452T	Insertion or replacement of a permanently implantable aortic counter pulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; aortic counter pulsation device and vascular hemostatic seal (Effective 01/01/17)
0453T	Insertion or replacement of a permanently implantable aortic counter pulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface (Effective 01/01/17)
0454T	Insertion or replacement of a permanently implantable aortic counter pulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode (Effective 01/01/17)
0455T	Removal of permanently implantable aortic counter pulsation ventricular assist system; complete system (aortic counter pulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes) (Effective 01/01/17)
0456T	Removal of permanently implantable aortic counter pulsation ventricular assist system; aortic counter pulsation device and vascular hemostatic seal (Effective 01/01/17)
0457T	Removal of permanently implantable aortic counter pulsation ventricular assist system; mechano-electrical skin interface (Effective 01/01/17)

0458T	Removal of permanently implantable aortic counter pulsation ventricular assist system; subcutaneous electrode (Effective 01/01/17)
0459T	Relocation of skin pocket with replacement of implanted aortic counter pulsation ventricular assist device, mechano- electrical skin interface and electrodes (Effective 01/01/17)
0460T	Repositioning of previously implanted aortic counter pulsation ventricular assist device, subcutaneous electrode; (Effective 01/01/17)
0461T	Repositioning of previously implanted aortic counter pulsation ventricular assist device, subcutaneous electrode; aortic counter pulsation device (Effective 01/01/17)
0462T	Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counter pulsation ventricular assist system, per day (Effective 01/01/17)
0463T	Interrogation device evaluation (in person) with analysis, review, and report, includes connection, recording and disconnection per patient encounter, implantable aortic counter pulsation ventricular assist system, per day (Effective 01/01/17)
HCPCS CODES	
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only (Effective 01/01/18)
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 only
Q0487	Leads (pneumatic/electrical) for use with any type of 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 or 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, other than lithium-ion, 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/bag for use to carry external peripheral components of any type of 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
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 02/28/2006

Date	Explanation & Changes
01/01/07	• No change
01/01/08	• No change
04/15/09	• Updated verbiage
07/01/12	• Updated codes
10/13/15	• Removed deleted code Q0505. Added codes 33977, 33978, 33980, 33983, 33990, 33991, 33992, 33993, 93750, and Q0506-Q0509 • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
01/27/17	• Added effective 01/01/2017 new codes 0451T-0463T as non-covered • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
02/22/18	• Added effective 1/1/18 new codes 33927, 33928, & 33929 (total artificial heart) as covered for all product lines • Added effective 1/1/18 new code Q0477 • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/01/2021	• Medical policy placed on the new Paramount Medical Policy Format
07/01/2021	• Policy reviewed and updated to reflect most current clinical evidence • Policy updated to the most current CMS NCD for the Elite/ProMedica Medicare Plan • No change in the coverage/noncoverage criteria • Added new 2021 procedure codes 33995 and 33997 • Procedures 33990, 33991, 33992, 33993 revised with new text
02/03/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/30/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
02/01/2024	• Medical policy placed on the new Paramount Medical Policy Format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review