MEDICAL POLICY	Cardiac: Ventricular Assist (VAD/pVAD/LVAD) and Artificial Heart (Biventricular) Devices
Effective Date: 1/1/2022  1/1/2022 Medical Officer Date	Medical Policy Number: 79 Medical Policy Committee Approved Date: 10/03; 8/04; 9/05; 7/07; 5/09' 12/10; 2/11; 4/12; 12/12; 1/13, 8/13; 10/14; 10/15; 12/16; 12/17; 4/18; 12/18; 8/19; 2/2020; 08/2020; 12/2020; 11/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Ventricular Assist Devices (VADs) and Left Ventricular Assist Devices (LVADs)

- For all lines of business, the policy criteria for ventricular assist devices and left ventricular assist devices are primarily based on the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1)(Effective 10/30/2013)[1]
- For all lines of business, VAD destination therapy must be performed at a Medicare approved facility. A complete list of Medicare approved facilities is available here.

I. Ventricular assist devices (VAD's), left ventricular assist device (LVAD) may be considered **medically necessary and covered** subject to criteria listed below.

A. Post-Cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions (see Regulatory Status section).

B. Bridge-to-transplant (effective for services performed on or after January 22, 1996)

VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions (see Regulatory Status section). All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

1. The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist or is a candidate for transplant.
2. The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed (if on a list) prior to implantation of the VAD.

   Note: Patient may be currently listed and approved for heart transplantation, OR is a transplant candidate, OR the VAD will be used as destination therapy.

C. Destination Therapy (effective for services performed on or after October 1, 2003)

Destination therapy is for patients that require permanent mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose (see Regulatory Status section).

D. Patient Selection (effective November 9, 2010)

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation, and meet all of the following conditions:

1. Have 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;
2. Have a left ventricular ejection fraction (LVEF) of less than 25%.
3. Have demonstrated functional limitation with a peak oxygen consumption of $\leq$14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

E. Facility Criteria (effective October 30, 2013)

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

1. At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs as BTT or DT over the course of the previous 36 months with activity in the last year.
2. 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.
3. A VAD program coordinator.
4. A social worker.
5. A palliative care specialist.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services. Web Site: http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp

II. All other indications for the use of VADs not otherwise listed remain **non-covered**, except in the context of Category B investigational device exemption clinical trials or as a routine cost in clinical trials defined 310.1 of the NCD Manual.

Artificial Hearts and Related Devices

The policy criteria for artificial hearts for all lines of business are based on the Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9)(Effective 10/30/2013).[2]

III. Artificial hearts and related devices may be considered **medically necessary and covered** subject to criteria listed below.

A. Bridge-to-transplant (BTT) (effective for services performed on or after May 1, 2008)

An artificial heart for bridge-to-transplantation (BTT) is covered when performed under coverage with evidence development (CED) when a clinical study meets all of the criteria listed below. The clinical study must address at least one of the following questions:

1. 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?
2. What will be the average time to device failure when the device is made available to larger numbers of patients?
3. 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?

The clinical study must meet all of the criteria stated in Section C of this policy. The above information should be mailed to: Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services (CMS), Re: Artificial Heart, Mailstop S3-02-01, 7500 Security Blvd, Baltimore, MD 21244-1850.

Clinical studies that are determined by CMS to meet the above requirements will be listed on the CMS Web site at: http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html.

B. Destination therapy (DT) (effective for services performed on or after May 1, 2008)

An artificial heart for destination therapy (DT) is covered when performed under CED when a clinical study meets all of the criteria listed below. The clinical study must address at least one of the following questions:

1. 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?
2. What will be the average time to device failure when the device is made available to larger numbers of patients?
3. 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?

The clinical study must meet all of the criteria stated in Section C of this policy. The above information should be mailed to: Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services, Re: Artificial Heart, Mailstop S3-02-01, 7500 Security Blvd, Baltimore, MD 21244-1850.

Clinical studies that are determined by CMS to meet the above requirements will be listed on the CMS Web site at: http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html.

C. Clinical study criteria:

1. The study must be reviewed and approved by the Food and Drug Administration (FDA).
2. The principal purpose of the research study is to test whether a particular intervention potentially improves the participantsi¦ health outcomes.
3. 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.
4. The research study does not unjustifiably duplicate existing studies.
5. The research study design is appropriate to answer the research question being asked in the study.
6. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
7. 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.
8. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
9. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED.
10. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy 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.
11. The clinical research study is registered on the www.ClinicalTrials.gov Web site by the principal sponsor/investigator as demonstrated by having a Clinicaltrials.gov Identifier.
12. 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.
13. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally under-represented 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 under-represented populations, the protocol must discuss why these criteria are necessary.

14. 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.

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 above-listed research questions. The principal investigator of an artificial heart clinical study seeking Medicare payment should submit the following documentation to 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 above questions related to artificial hearts;
6. Complete contact information (phone number, email address, and mailing address); and,
7. Clinicaltrials.gov Identifier.

IV. All other indications for the use of artificial hearts not otherwise listed remain **non-covered**, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

Percutaneous Ventricular Assist Devices (pVADs)

The policy criteria for percutaneous ventricular assist devices for all lines of business is based on the Local Coverage Article (LCA) for Percutaneous Endovascular Cardiac Assist Procedures and Devices (A52967)(Effective Date: 10/1/2015)[3] and the FDA approved indications for use (link).[4]

Note: Effective for dates of service on/after February 3, 2014. This service will only be covered when the FDA approval guidelines are strictly followed.

V. A percutaneous ventricular assist device (pVAD)(i.e., Impella) may be considered **medically necessary and covered** when **all** of the following (A. -C.) criteria are met:
   A. External counterpulsation (intraaortic balloon pump, IABP) is not expected to be sufficient; **and**
   B. The patient is experiencing **at least one** of the following (1.-3.):
      1. Severe coronary artery disease and depressed left ventricular ejection fraction and is undergoing high risk percutaneous coronary interventions (PCI) and **all** of the following criteria (a.-c.) are met:
         a. Patient is hemodynamically stable; **and**
         b. The device is placed in the patient for fewer than 6 hours; **and**
         c. A heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option; **or**
      2. Cardiogenic shock when **both** of the following criteria have been met (a.-b.):
         a. Patient is not responsive to optimal medical management and conventional treatment measures (e.g. volume loading and use of pressors and inotropes, with or without IABP); **and**
         b. Either of the following criteria are met:
            i. Shock occurs **either** fewer than 48 hours following acute myocardial infarction or open heart surgery, **or**
            ii. Shock occurs in the setting of cardiomyopathy, including peripartum myopathy, including peripartum cardiomyopathy, or myocarditis; **or**
      3. Severe decompensated heart failure *with* threatening multi-organ failure; **and**
   C. The device remains placed in the patient temporarily (i.e. no more than 4 days for the Impella 2.5 and Impella CP; no more than 6 days for the Impella 5.0 and Impella LD; and no more than 14 days for Impella RP).

VI. A percutaneous ventricular assist device (pVAD) (i.e., Impella) is considered **investigational and is not covered** when criterion V. above is not met.

VII. A percutaneous ventricular assist device (pVAD) (i.e., Impella) is considered **investigational and not covered**, including but not limited to, when any of the following contraindications are present:

- Mural thrombus in the left ventricle
- Mechanical aortic valve or heart constrictive device
- Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less)
- Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2)
- Severe peripheral arterial disease that precludes the placement of an Impella Catheter
- Combined cardiorespiratory failure
- Presence of an atrial or ventricular septal defect (including post-infarct VSD)
- Left ventricular rupture
- Cardiac tamponade

BILLING GUIDELINES

Payment Policy

Payment on a fee schedule basis is required for prosthetic devices by Section 1834(h) of the Social Security Act. The following codes are being added December 2012 to the HCPCS Quarterly Update with an effective date of April 1, 2013:

Q0507 Miscellaneous Supply or Accessory for Use with an External 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

Per the Centers for Medicare and Medicaid Services (CMS) Medicare claims Processing Manual, Chapter 32 – Billing requirements for Special Services (320.3.5):[5]

"Effective April 1, 2013, claims for replacement of accessories and supplies for VADs implanted in patients who were not eligible for coverage under Medicare Part A or had other insurance that paid for the device and hospital stay at the time that the device was implanted, but are now eligible for coverage of the replacement supplies and accessories under Part B, should be submitted using HCPCS code Q0509. Those claims will be manually reviewed.

In rare instances it may be appropriate to pay for replacement of supplies and accessories for external VADs used by patient who are discharged from the hospital. In addition, in some rare instances, it may be necessary for a patient to have an emergency back-up controller for an external VAD. Coverage of these items is at the discretion of the contractor. Claims for replacement of supplies and accessories used with an external VAD that are furnished by suppliers should be billed to the B MACs. Claims for replacement of supplies and accessories used with an external VAD that are furnished by hospitals and other providers should be billed to the A MACs. Effective April 1, 2013, these items should be billed using code Q0507 so that the claims can be manually reviewed.

In rare instances it may be appropriate to pay for replacement of supplies and accessories for external VADs used by patient who are discharged from the hospital. In addition, in some rare instances, it may be necessary for a patient to have an emergency back-up controller for an external VAD. Coverage of these items is at the discretion of the contractor. Claims for replacement of supplies and accessories used with an external VAD that are furnished by suppliers should be billed to the B MACs. Claims for replacement of supplies and accessories used with an external VAD that are furnished by hospitals and other providers should be billed to the A MACs. Effective April 1, 2013, these items should be billed using code Q0507 so that the claims can be manually reviewed.

Claims for replacement supplies or accessories used with VADs that do not have specific HCPCS codes and do not meet the criteria of codes Q0507 and Q0509 should be billed using code Q0508."

NOTE: When determined to be medically necessary, dressings used with VADs are covered under the prosthetic device benefit as a supply necessary for the effective use of the VAD/prosthetic device.

Claims for dressings necessary for the effective use of a VAD should be billed using the appropriate miscellaneous VAD supply code, depending upon whether the patient was eligible for coverage under Medicare Part A at the time that the VAD was implanted. The claims processing jurisdiction for dressings used with VADs is identical to that of other VAD replacement supplies and accessories and does not fall under Durable Medical Equipment MAC jurisdiction.[5]

Medicare Billing Guidelines for Ventricular Assist Device:

The Left Ventricular Assist System (LVAS) is implanted in an inpatient setting and Medicare payment is made under Part A for:

- Hospital inpatient services; and
- Supplies and all necessary accessories for the LVAS (provided in the inpatient setting).

Medicare payment is made under Part B for additional medically necessary supplies and replacement accessories required after the patient has been discharged from the hospital.
Claims for replacement of supplies and accessories used with the LVAS that are furnished by suppliers should be billed to the local carriers. Claims for replacement of supplies and accessories that are furnished by hospitals should be billed to the intermediary. It is the responsibility of the local carrier or intermediary to determine whether the replacement supplies and accessories can be covered and to provide instructions, as needed, on how often these items can be replaced.

Manufacturer(s) may have erroneously suggested that CMS instructions in AB-02-152 allow providers to bring a recently discharged patient back for an outpatient visit to replace the LVAD equipment that was furnished under Part A in order to receive extra payment under Part B. This erroneous suggestion may lead hospitals to believe that they can get extra Part B payment in cases where the replacement or supplies are not medically necessary.

CMS reminds providers, suppliers, and Medicare intermediaries and carriers that payment under Part B can only be made for replacement of components and accessories that are reasonable and necessary. If the intermediary or carrier gets claims for replacement of items within a relatively short period of time following discharge from the hospital, they will be aware that this may just be an attempt to obtain additional reimbursement for the LVAD under Part B (in those cases where there is not a true replacement need).

For example, the batteries or power sources for these devices require periodic replacement. The manufacturers have indicated that these items should last approximately 6 months to a year, depending on the brand of device. Therefore, it would not be reasonable and necessary to replace these items any time before these minimum, expected product lifetimes have expired. For other components and accessories, the product lifetimes will be even longer. Cases without medical need for replacement would be considered double billing.[6]

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
Artificial Heart	
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)
Ventricular Assisted Devices (VAD/pVAD/LVAD)	
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
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
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
Accessories	
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
No Prior Authorization Required	
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Removal of ventricular assist device; extracorporeal, biventricular
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
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

Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only
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 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 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
Not Covered	
~~0451T~~	**TERMED 12/31/2021** ~~Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)~~
~~0452T~~	**TERMED 12/31/2021** ~~Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; aortic counterpulsation device and vascular hemostatic seal~~
~~0453T~~	**TERMED 12/31/2021** ~~Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface~~
~~0454T~~	**TERMED 12/31/2021** ~~Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode~~
~~0455T~~	**TERMED 12/31/2021** ~~Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)~~
~~0456T~~	**TERMED 12/31/2021** ~~Removal of permanently implantable aortic counterpulsation ventricular assist system; aortic counterpulsation device and vascular hemostatic seal~~
~~0457T~~	**TERMED 12/31/2021** ~~Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface~~
~~0458T~~	**TERMED 12/31/2021** ~~Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode~~
~~0459T~~	**TERMED 12/31/2021** ~~Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano-electrical skin interface and electrodes~~
~~0460T~~	**TERMED 12/31/2021** ~~Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode~~
~~0461T~~	**TERMED 12/31/2021**

	~~Repositioning of previously implanted aortic counterpulsation ventricular assist device; aortic counterpulsation device~~
~~0462T~~	**TERMED 12/31/2021** ~~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 counterpulsation ventricular assist system, per day~~
~~0463T~~	**TERMED 12/31/2021** ~~Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day~~
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
33999	Unlisted procedure, cardiac surgery
L8698	Miscellaneous component, supply or accessory for use with total artificial heart system
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

DESCRIPTION

Ventricular Assist Device (VAD)

A ventricular assist device (VAD) or left ventricular device (LVAD) is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood. Improvement in the performance of the native heart may allow the device to be removed.

Artificial Heart

An artificial heart is a biventricular replacement device which requires removal of a substantial part of the native heart, including both ventricles. Removal of this device without the transplant of a replacement heart is not compatible with life.

Percutaneous Ventricular Assist Device (pVAD)

A pVAD differs from a VAD in that it is worn outside of the body and connects to the heart via a vein in the thigh. The device has a mechanical pump that gives short-term support (few hours up to 15 days) to the heart; thus giving the heart time to strengthen following heart failure, heart surgery, or heart attack.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

U.S. Food and Drug Administration (FDA)

The FDA has approved several ventricular assist (VAD/pVAD/LVAD) and artificial heart (biventricular) devices. This list may not be all inclusive. See the FDA devices database for more information.[7]

Device Name & Manufacturer	Device Type	Indication
HeartWare® Ventricular Assist System by Heartware Intl., Inc.	VAD	Bridge to transplant- for use in or out of hospital
Impella 2.5 by Abiomed Inc.	pVAD	A temporary (< 6 hours) ventricular support device indicated for use during high-risk PCI performed in elective or urgent hemodynamically stable patients with severe CAD and depressed LVEF, when the heart team (including a cardiac surgeon) has determined that high-risk PCI is the appropriate therapeutic option.
Impella 5.0 by Abiomed Inc.	pVAD	The IMPELLA 5.0 Catheters are intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. They are also intended to be used to

		provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The IMPELLA 5.0 Catheters also provide pressure measurements which are useful in determining intravascular pressure
Impella CP by Abiomed Inc.	pVAD	For partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The Impella 2.5 Plus Catheter also provides pressure measurements which are useful in determining intravascular pressure.
Impella RP by Abiomed Inc.	pVAD	The Impella RP System is indicated for providing circulatory assistance for up to 14 days in pediatric or adult patients with a body surface area ≥1.5 m2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.
TandemHeart by Cardiac Assist Inc.	pVAD	The TandemHeart System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. Intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant, etc.).
HeartMate II® by Thoratec Corp.	LVAD	Bridge to transplant and destination therapy
Novacor® by World Heart, Inc.	LVAD	Bridge to transplant
Thoratec® IVAD by Thoratec Corp.	BiVAD	Bridge to transplant and post-cardiotomy
EXCORE® Pediatric System by Berlin Heart, Inc.	BiVAD	Bridge to transplant pediatric (newborns to teens)
SynCardi Temporary Total Artificial Heart (TAH) by SynCardia Systems, Inc.	Temporary total artificial heart	Bridge to transplant—for use inside the hospital
AbioCOR® Total Artificial Heart (TAH) by AbioMed, Inc.	Implantable replacement heart system	Destination therapy

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