NO. 91509

VENTRICULAR ASSIST DEVICES & ARTIFICIAL HEARTS

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy addresses ventricular assist devices and artificial hearts.

Related policies: None identified.

I. MEDICAL NECESSITY CRITERIA

Advance Care Planning Assessment: 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.

A. Left ventricular Assist Devices (LVADS)

1. **Extracorporeal.** Insertion of an extracorporeal left ventricular assist device is considered medically necessary when the applicable InterQual® criteria are met:

   InterQual®
   CP:Procedures
   Subset: ***Left Ventricular Assist Device (LVAD) Insertion***

Requested Service: Left Ventricular Assist Device (LVAD) Insertion

2. **Intracorporeal**. Insertion of an intracorporeal left ventricular assist device is considered medically necessary when the applicable InterQual® criteria are met:

   InterQual®
   CP:Procedures
   Subset: *Left Ventricular Assist Device (LVAD) Insertion*
   Requested Service: Left Ventricular Assist Device (LVAD) Insertion

3. **Percutaneous**. Insertion of a percutaneous left ventricular assist device (e.g., the TandemHeart and the Impella) is 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.

B. 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 m2 for the treatment of acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

C. **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.

D. Artificial Hearts:

1. **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.
2. **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.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Ventricular Assist Devices 20.9.1	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	*Billing and Coding: Artificial Hearts and Percutaneous Endovascular Cardiac Assist Procedures and Devices A59657
Novitas Solutions, Inc.	None identified
Palmetto GBA	*Billing and Coding: Percutaneous Ventricular Assist Device A53986 A53988
WPS Insurance Corporation	*Independent Diagnostic Testing Facilities-physician supervision and technician requirements A54953

*Not in direct support of an LCD.

III. BACKGROUND

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.

Beneficiaries receiving a ventricular assist device (VAD) 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 informed decision making. 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:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs over the course of the previous 36 months with activity in the last year
- 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 placement of a VAD
- A VAD program coordinator
- A social worker
- A palliative care specialist

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.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
European Association for Cardio-Thoracic Surgery Society of Thoracic Surgeons	EACTS/STS/AATS Guidelines on temporary mechanical circulatory

American Association for Thoracic Surgery	support in adult cardiac surgery (Potapov EV et al., 2025)
American Society of Echocardiography	Recommendations for Multimodality Imaging of Patients With Left Ventricular Assist Devices and Temporary Mechanical Support: Updated Recommendations from the American Society of Echocardiography (Estep JD et al., 2024)
International Society for Heart and Lung Transplantation (ISHLT)	The 2023 ISHLT Guidelines for Mechanical Circulatory Support: A 10-Year Update (Saeed D et al., 2023) The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support (Bernhardt AM et al., 2023)
Heart Failure Society of America (HFSA)	HFSA Expert Consensus Statement on the Medical Management of Patients on Durable Mechanical Circulatory Support (Trachtenberg B et al., 2023)
American Heart Association (AHA)	Device Therapy and Arrhythmia Management in Left Ventricular Assist Device Recipients: A Scientific Statement From the American Heart Association (Gopinathannair R et al., 2019) Cardiopulmonary Resuscitation in Adults and Children With Mechanical Circulatory Support: A Scientific Statement From the American Heart Association (Peberdy MA et al., 2017)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

For ventricular assist devices (VADs) and artificial hearts, FDA relies on a small, well-defined set of Class III product codes, almost all reviewed by the Cardiovascular Devices panel. These codes directly correspond to FDA-approved devices used for bridge-to-transplant, destination therapy, and temporary or pediatric indications.

The core FDA product codes are:

DSQ – Ventricular (Assist) Bypass

LOZ – Artificial Heart

OZD – Temporary non-roller type left heart support blood pump

QNR – Blood Pump For Ecmo, Long-Term (> 6 Hours) Use

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
DSQ – Ventricular (Assist) Bypass		
NOVACOR LVAS (Worldheart, Inc.)	P980012	09/29/1998
HEARTMATE VE LVAS (Thoratec Corp)	P920014	09/30/1994
ABIOMED BVS(R) 5000 BI-VENTRICULAR SUPPORT SYSTEM (Abiomed Cardiovascular, Inc.)	P900023	11/20/1992
THORATEC(R) VENTRICULAR ASSIST DEVICE (VAD) SYSTEM (Thoratec Laboratories Corp.)	P870072	12/20/1995
CentriMag Circulatory Support System (Abbott)	P170038	12/06/2019
HeartMate 3™ Left Ventricular Assist System (ABBOTT MEDICAL)	P160054	08/23/2017
EXCOR Pediatric Ventricular Assist Device (Berlin Heart, Inc.)	P160035	06/06/2017
HEARTWARE VENTRICULAR ASSIST SYSTEM (Medtronic)	P100047	11/20/2012
LOZ – Artificial Heart		
SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T) (Syncardia Systems, LLC)	P030011 P030011 S097	10/15/2004 02/20/2026
OZD – Temporary non-roller type left heart support blood pump		
IMPELLA 2.5 System Impella CP with SmartAssist; Impella 5.5 with SmartAssist (Abiomed, Inc.)	P140003 P140003 S136	03/23/2015 12/19/2025
QNR – Blood Pump For Ecmo, Long-Term (> 6 Hours) Use		
VitalFlow Console (Medtronic, Inc.)	K250199	05/20/2025
LifeSPARC System (Cardiacassist, Inc.)	K233736	01/19/2024
CentriMag™ Acute Circulatory Support System (ABBOTT MEDICAL)	K234118	01/26/2024

VitalFlow™ Console (Michigan Critical Care Consultants, Inc. (D.B.A Mc3 Inc.))	K230364	08/25/2023
CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System (Abbott (Formerly Thoratec Corporation))	K222038	12/08/2022
VitalFlowTM Centrifugal Pump (Michigan Critical Care Consultants, Inc. (D.B.A Mc3 Inc.))	K223898	08/25/2023
LifeSPARC System (Cardiacassist, Inc.)	K211830	11/15/2022
TandemHeart Pump and Escort Controller (Cardiacassist, Inc.)	K202751	03/26/2021

Note: These medical devices may have supplements. The device description/function or indication may have changed. Be sure to look at the supplements to get an up-to-date information on device changes. The labeling at time of approval of the original PMA or panel track supplement may not represent the most recent labeling.

VI. CODING

See also Priority Health Billing Policy No. 033 Surgical Implants and Devices

See also Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes ("T" codes)

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 - *Prior 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

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, 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, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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/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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines and position statements

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SUMMARY OF CHANGES

Changes:

- Insertion of an extracorporeal left ventricular assist device is considered medically necessary when the applicable InterQual® criteria are met.
- Insertion of an intracorporeal left ventricular assist device is considered medically necessary when the applicable InterQual® criteria are met:

Past committee review dates: 08/2005, 06/2006, 06/2007, 06/2008, 10/2008, 10/2009, 10/2010, 10/2011, 10/2012, 10/2013, 11/2014, 11/2015, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 02/2021, 02/2022, 02/2023, 02/2024, 02/2025, 05/2025