Clinical Policy: Ventricular Assist Devices

Reference Number: WA.CP.MP.46
Last Review Date: 04/24
Effective Date: 06/01/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

A ventricular assist device (VAD) is a mechanical pump that helps the heart when it is too weak to pump blood through the body. VADs are designed to enhance blood flow to the body's organs, either in conjunction with, or as a replacement for, a damaged or diseased heart. A VAD can be used in both an acute and subacute setting for patients who have poor heart function as a temporary measure as either a "bridge to recovery" or a "bridge to transplant." When used as a "bridge to transplant," a VAD can help a patient survive until a heart transplant can be performed. When used as a "bridge to recovery," a VAD is often used as an adjunctive device in high-risk percutaneous coronary interventions.

Policy/Criteria

It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority billing guidelines, that all FDA approved VADs, when used according to their FDA labeled indications (including body size recommendations), are considered medically necessary in the following situations:

I. Implantable VADs with FDA approval are considered **medically necessary** in any of the following situations (A, B or C):

A. For use as a bridge to transplantation when *both* of the following requirements are met:
   1. Member is currently listed as a heart transplantation candidate or under evaluation to determine eligibility for heart transplantation
   2. Member is not expected to live until a donor heart is available

B. For use in the post-cardiotomy setting in members who are unable to be weaned off cardiopulmonary bypass.

C. For use as a destination therapy when all of the following requirements are met:
   1. The member is at end-stage heart failure
   2. There is documented ineligibility for human heart transplantation
   3. The member has either of the following:
      - New York Heart Association (NYHA) class III* or IV* for at least 28 days and received at least 14 days support with an intra-aortic balloon pump or is dependent on intravenous inotropic agents, with two failed weaning attempts
      - NYHA class IV* heart failure for at least 60 days

      *NYHA Class III – marked limitation of physical activity; less than ordinary activity leads to symptoms

      *NYHA Class IV – inability to carry on any activity without symptoms; symptoms may be present at rest

4. Destination therapy must be done at a CMS-approved VAD destination therapy facility

II. Percutaneous left ventricular assist devices (pVADs) with FDA approval are considered **medically necessary** in any of the following situations (A or B):
   A. Providing short-term circulatory support in cardiogenic shock
   B. As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk patients:
      1. Members undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35%
      2. Members with three vessel disease and diastolic ejection fraction less than 30%

III. Pediatric-specific VADs (age 0-18 years) are considered **medically necessary** if FDA approved and both of the following criteria are met:
   A. The child has documented end-stage left ventricular failure
   B. An age and size-appropriate VAD will be used until a donor heart can be obtained

IV. Any requests for VADs not meeting the above criteria will be considered **not medically necessary**.

Background
Ventricular assist devices (VADs) have proven beneficial to myocardial function through improvement in myocardial contractile performance, reversal of down regulation of beta-receptors in heart failure, restoration of the ability of the heart to respond to the inotropic effects of sympathetic stimulation, normalization of chamber geometry and reduction of myocardial fibrosis, hypertrophy, and disruption in cytoskeletal proteins. These benefits suggest that failing human myocytes are capable of undergoing beneficial functional and electrophysiological changes and can have increased contractile strength in the presence of hemodynamic unloading and improved neurohumoral and circulatory derangements. This remodeling takes approximately 40 days and shows both clinical benefit and improvement in quality of life.

Since 2000, there have been improved outcomes in VAD implantation in the pediatric population. Early experience involved the most critically ill children who were often near death at the time of VAD implantation. More recently, centers' increasing experience with surgical techniques, timing, and postoperative care; the use of more long-term devices over time; and refinements in patient selection have resulted in improved outcomes, despite the increasing use of VADs in smaller and more complex patients. Further study is warranted to optimize criteria for pediatric patient and device selection.

In one study reported by Blume, et al[2], 86% of pediatric patients who received a VAD were successfully bridged to transplantation from 2000 to 2003. Prior to 2000, only 63% of pediatric patients were successfully bridged to transplantation. The subgroups including patients with congenital heart disease and younger patients, who are rarely large enough for most long-term assist devices, did not have similar success rates when compared to the remainder of the population.

A prospective multi-institutional investigational device exemption trial compared patients with the Berlin Heart EXCOR with a control group supported on extracorporeal membrane oxygenation (ECMO). Between May 2009 and December 2010, a total of 48 patients ≤16 years of age met the inclusion criteria and were separated into two cohorts according to body surface area (cohort 1, <0.7 m2; cohort 2, ≥0.7 m2) with 24 patients in each group. The median survival time for cohorts 1 and 2 (>174 and 144 days, respectively) far exceeded that of ECMO (cohort 1, 13 days; cohort 2, 10 days; *P*<0.001 by log-rank test). Based on the results of this trial, the Berlin Heart EXCOR was granted HDE approval as a device to provide long-term mechanical circulatory support as a bridge to cardiac transplantation in children with severe left or biventricular dysfunction.[9]

The Post Approval Surveillance report released on the EXCOR Pediatric VAD showed positive contemporary results; reported stroke rate 11% and mortality rate of 12.5%, exceeding primary objectives.

There have been several pediatric VADs approved by the FDA, i.e., The HeartAssist 5 Pediatric VAD, previously known as the DeBakey BAD Child Left Ventricular Assist System and the Berlin Heart's EXCOR VAD.

American Heart Association (AHA)/American College of Cardiology Foundation (ACC)/ Heart Failure Society of America (HFSA)[18]
The most recent AHA/ACC/HFSA Guideline for the Management of Heart Failure suggests that durable LVADs (left ventricular assist devices) should be considered in patients with NHYA class IV symptoms who are dependent on IV inotropes or temporary MCS (mechanical circulatory support). In patients who have NYHA class IV symptoms despite optimal medical therapy, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality.

Temporary MCS including the use of percutaneous and extracorporeal ventricular assist devices, are reasonable as a 'bridge to recovery" or "bridge to decision." In patients with cardiogenic shock, temporary MCS is reasonable when end-organ function cannot be maintained by pharmacologic means to support cardiac function.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle

CPT® Codes	Description
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 devices pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist devices 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 ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion

HCPCS Codes	Description
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 VAD, replacement only
Q0486	Monitor control cable for use with electric/pneumatic VAD, 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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	07/19	07/19
Annual review. Reference updated.	03/20	04/20
Minor changes to clarify clinical criteria	04/20	05/20
Annual review. Added information regarding pediatric VADs. References reviewed and updated. Removed ICD-10 code Z94.1 and added Z76.82. Replaced all instances of "member" with members/enrollees. Revised description of CPT 33990, 33991 and 33992.	03/21	04/21
Annual review. Updated Description. Added age for pediatric services. Updated Background. Reviewed and updated References.	03/22	03/22
Annual review. Background and note updated with no clinical significance. Section III reworded. Removed ICD codes. References updated.	03/23	03/23
Annual review. References reviewed and updated. Minor rewording in description with no impact on criteria. Added FDA approval requirement to Sections I and II per billing guidelines. Updated section I. A. language for clarity, no impact on criteria.	03/24	04/24

References

1. Washington State Health Care Authority. Physician-related Services/Health Care Billing Guide. https://www.hca.wa.gov/assets/billers-and-providers/Physician-related-services-bg-20240301.pdfRevision effective February 15, 2024.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.