Clinical Policy: Ventricular Assist Devices

Reference Number: CP.MP.46
Date of Last Revision: 02/23

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 bodily 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

I. It is the policy of health plans affiliated with Centene Corporation® that all FDA approved ventricular assist devices (VADs), when used according to their FDA labeled indications (including body size recommendations), are considered **medically necessary** when meeting the following criteria:

A. For implantable VADs, none of the following contraindications are applicable:
   1. Life expectancy in the absence of heart disease ≤ two years;
   2. Malignancy within five years that is expected to significantly limit survival;
   3. Irreversible renal or hepatic dysfunction, severe obstructive pulmonary disease, or other systemic disease with multi-organ involvement;
   4. A pattern of demonstrated noncompliance or lack of sufficient care-giver support which would place a VAD at serious risk of failure;
   5. Active substance use or dependence including current tobacco use, vaping, marijuana use (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk reduction behaviors (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable). Serial blood and urine testing may be used to verify abstinence from substances that are of concern;

B. Has one of the following indications:
   1. Post-cardiotomy for support of blood circulation;
   2. Bridge to transplant for members/enrollees who are awaiting heart transplant (or undergoing evaluation to determine candidacy for heart transplant) and not expected to survive until a donor heart can be obtained;
   3. Destination therapy for members/enrollees with end-stage heart failure (NYHA Class IV end-stage left ventricular failure for at least 90 days with a life expectancy of ≤ two years) who are ineligible for heart transplant due to age or co-morbidities and all of the following:
      a. Meets one of the following:
         i. No response to optimal medical management (including beta-blockers and ACE inhibitors, if tolerated) for at least 45 of the last 60 days;
         ii. Balloon pump-dependent for ≥ seven days;

iii. IV inotrope-dependent for ≥ 14 days;
iv. Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes and meet one of the following criteria:
1) No response to optimal medical management (including beta-blockers and ACE inhibitors, if tolerated), for at least 45 out of the last 60 days;
2) Presence of advanced heart failure for at least 14 days with dependence on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least seven days;

b. Left ventricular ejection fraction (LVEF) ≤ 25%;
c. Functionally limited with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent, or physically unable to perform the test.

II. It is the policy of health plans affiliated with Centene Corporation® that pediatric-specific ventricular assist devices are considered **medically necessary** if FDA approved or approved under the FDA Humanitarian Device Exemption (HDE) guidelines and used in accordance with the device specific inclusion and exclusion criteria, including body size recommendations. The following criteria must be met:
A. Age ≤ 16 years, or age specific to FDA approved guidelines;
B. Severe isolated left ventricular or biventricular dysfunction;
C. As a bridge to heart transplant for members/enrollees who require circulatory support.

Note: A humanitarian device exemption is granted by the FDA. A humanitarian use device (HUD) is a device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States annually. A HUD may only be used in facilities that have established a local institutional review board to supervise clinical testing of devices and after an independent review board has approved the use of the device to treat or diagnose the specific disease.[19]

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

CPT® Codes	Description
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 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

HCPCS Codes	Description
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed		12/09
Updated VAD criteria to current CMS NCD guidelines for artificial hearts and related devices Coding implications and references reviewed and updated Added criteria for Pediatric VADs based on HDE approvals Specialist review: Internal medicine, cardiology	05/13	05/13
References reviewed and updated	05/14	05/14
Updated formatting, no criteria review or changes	01/15	
References reviewed and updated	04/15	04/15
Template updated; References reviewed and updated; added contraindications per ISHLT guidelines and Heart Assist 5 instructions for use. Specialist reviewed.	04/16	04/16
Reviewed references and updated. Added a position statement from the American Cardiology Foundation /American Heart Association, as well as National Health Service on VADs. Restructured criteria in section I for clarity. Changed I.A.1. to specify that the contraindication of illness causing life expectancy less than 2 years is different than heart failure.	04/17	04/17
References reviewed and updated. Codes reviewed and updated.	02/18	02/18
Clarified in section I.B.3.a., the phrase “failure to respond to” only applied to optimal medical management, and not balloon or inotrope dependence. Specified that balloon pump and inotrope requirements are ≥, and not exact. Changed “cardiac transplantation” to “heart transplant” for consistency.	05/18	
References reviewed and updated. Removed HeartAssist® Pediatric VAD as this device is no longer available.	02/19	02/19
References reviewed and updated. Specialist reviewed.	01/20	02/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review. References reviewed and updated. Removed ICD-10 code Z94.1 and added Z76.82. Replaced all instances of "member" with members/enrollees. Removed mention of Berlin Heart EXCOR Pediatric VAD under II.A as other pediatric VAD's are being approved. Added "if FDA approved or approved under the FDA HDE guidelines and used in accordance with the device specific inclusion/exclusion criteria, including body size." to II. Added "or age specific to FDA approved guidelines to II.A.1. Changed II.A.3 from "Is a candidate for heart transplant" to "As a bridge to heart transplant." Revised description of CPT-33990, 33991 and 33992.	01/21	02/21
Annual review. References reviewed and updated to AMA format. Changed "review date" in the header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date." Added "Cardiac Index (CI) <2.2 L/min/m^2, while not on inotropes and meet one of the following criteria: 1. No response to optimal medical management (including beta-blockers and ACE inhibitors, if tolerated, for at least 45 out of the last 60 days; 2. Presence of advanced heart failure for at least 14 days with dependence on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days" to Policy/Criteria I.B.4 to reflect update to NCD Ventricular Assist Devices 20.9.1 per CMS. Background updated with most recent AHA scientific statement regarding placement of MCS (mechanical circulatory support) devices with no impact on criteria. Reviewed by specialist.	02/22	02/22
Annual review. Updated substance use contraindication in criteria I.A.5. Removed criteria III. regarding requests not meeting the above criteria are not considered medically necessary. Background and note updated with no clinical significance. Removed ICD codes. References reviewed, updated, and reformatted. External specialist review.	02/23	02/23

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correction appears in Eur Heart J. 2016 Dec 30;:]. *Eur Heart J*. 2016;37(27):2129 to 2200. doi:10.1093/eurheartj/ehw128
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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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.