Clinical Policy: Ventricular Assist Devices

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Coding Implications
Revision Log

Description
A ventricular assist device (VAD) is a mechanical pump that helps a person's heart that is too weak to pump blood through the body. The VAD is designed to provide sufficient blood flow to the damaged or diseased heart. It is sometimes referred to as a "bridge to transplant" since it can help a patient survive until a heart transplant can be performed.

Policy/Criteria

I. It is the policy of Pennsylvania Health and Wellness® that all FDA approved VADs, when used according to their FDA labeled indications (including body size recommendations), are considered **medically necessary** when meeting the following:

A. For implantable VADs, none of the following contraindications:
   1. Life expectancy in the absence of heart disease ≤ 2 years;
   2. Malignancy within 5 years that is expected to significantly limit survival;
   3. Irreversible 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 abuse, including alcohol.

B. Has one of the following indications:
   1. Member/Enrollee is post-cardiotomy for support of blood circulation; *or*
   2. As a bridge to transplant for members/enrollees who are awaiting heart transplantation and not expected to survive until a donor heart can be attained; *or*
   3. As 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 < 2 years) who are ineligible for heart transplantation due to age or co-morbidities and all of the following:
      a. Meets one of the following:
         i. Failure to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or
         ii. Has been balloon pump-dependent for ≥7 days, or
         iii. IV inotrope-dependent for ≥14 days *and*
         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 7 days;
      b. Left ventricular ejection fraction (LVEF) < 25%, and
      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. Pediatric-specific VADs 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.

A. The following criteria must be met:

1. Members/Enrollees ≤ 16 years, or age specific to FDA approved guidelines, and
2. Severe isolated left ventricular or biventricular dysfunction, and
3. As a bridge to heart transplant for members/enrollees who require circulatory support.

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

Note: HDE is granted by 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 4,000 individuals in the United States annually. An HUD may only be used in facilities that have established a local institutional review board to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease.

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 is generally 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 2 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.[16]

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 College of Cardiology Foundation/American Heart Association[14]
Nondurable mechanical circulatory support including the use of a percutaneous and extracorporeal ventricular assist device is reasonable as a 'bridge to recovery.'

American Heart Association[24]
The most recent American Heart Association scientific statement suggests placement of temporary MCS (mechanical circulatory support) devices for patients with longer expected recovery times in the case of cardiogenic shock as "a bridge to recovery, bridge to transplantation or a bridge to decision strategy".

National Health Service
This organization currently funds the use of long-term VADs as bridge-to-transplant to support heart transplant candidates who are too unwell to undergo the procedure or are unlikely to survive in a good clinical state until a suitable donor heart becomes available.[15]

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 2021, 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
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 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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.82	Biventricular heart failure
I50.84	End stage heart failure
I50.9	Heart failure, unspecified
I97.0	Post-cardiotomy syndrome
Z95.811	Presence of heart assist device
Z76.82	Awaiting organ transplant status

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated. Removed HeartAssist® Pediatric VAD as this device is no longer available.	03/19	
References reviewed and updated. Specialist reviewed.	12/2020	
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.	10/2021	
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.	2/22/2023	

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