

Clinical Policy: Ventricular Assist Devices

Reference Number: CP.MP.46

Date of Last Revision: 02/24

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

- 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 \leq 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 caregiver 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. Short-term mechanical circulatory support as bridge to recovery for one of the following:
 - a. Myocardial infarction complicated by cardiogenic shock;
 - b. High-risk percutaneous coronary artery interventions;
 - c. Fulminant myocarditis presenting with cardiogenic shock;
 - d. Advanced heart failure with cardiogenic shock as a bridge-to-a-bridge;
 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 \leq

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 \geq seven days;
 - iii. IV inotrope-dependent for \geq 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) \leq 25%;
- c. Functionally limited with a peak oxygen consumption of \leq 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 \leq 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.

CLINICAL POLICY

Ventricular Assist Devices

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 al², 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 NYHA 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

CLINICAL POLICY
Ventricular Assist Devices

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 2023, 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 transeptal 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 |

CLINICAL POLICY
Ventricular Assist Devices

| HCPCS Codes | Description |
|-------------|---|
| 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 |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| Policy developed | | 12/09 |
| 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 \geq , 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 |
| 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 |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| 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 |
| Removed criteria I.B.1. for post-cardiotomy for support of blood circulation and replaced it with bridge to recovery criteria I.B.1.a. through d. | 05/23 | 05/23 |
| Annual review. Minor rewording in description with no impact to criteria. References reviewed and updated. | 02/24 | 02/24 |

References

1. Birks EJ, Mancini D. Treatment of advanced heart failure with a durable mechanical circulatory support device. UpToDate. www.uptodate.com. Published November 2022. Accessed January 3, 2024.
2. Blume ED, Naftel DC, Bastardi HJ, et al. Outcomes of children bridged to heart transplantation with ventricular assist devices: a multi-institutional study. *Circulation*. 2006;113(19):2313 to 2319. doi:10.1161/CIRCULATIONAHA.105.577601
3. National coverage determination: ventricular assist device (20.9.1). Centers for Medicare and Medicaid Services Web site: <https://www.cms.gov/medicare-coverage-database>. Published December 1, 2020. Accessed January 3, 2024.
4. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) Developed with the special contribution of the Heart Failure Association (HFA) of the ESC [published correction appears in *Eur Heart J*. 2016 Dec 30;:]. *Eur Heart J*. 2016;37(27):2129 to 2200. doi:10.1093/eurheartj/ehw128
5. Miller LW, Guglin M. Patient selection for ventricular assist devices: a moving target. *J Am Coll Cardiol*. 2013;61(12):1209 to 1221. doi:10.1016/j.jacc.2012.08.1029

6. Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: executive summary. *J Heart Lung Transplant*. 2013;32(2):157 to 187. doi:10.1016/j.healun.2012.09.013
7. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE). DeBakey VAD Child Ventricular Assist Device System. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H030003>. February 25, 2004. Accessed January 3, 2024.
8. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE). EXCOR Pediatric Ventricular Assist Device. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=h100004>. Published December 16, 2011. Accessed January 3, 2024.
9. Vanderpluym CJ, Fynn-Thompson F, Blume ED. Ventricular assist devices in children: progress with an orphan device application. *Circulation*. 2014;129(14):1530 to 1537. doi:10.1161/CIRCULATIONAHA.113.005574
10. Jeevanandam V, Eisen H. Short-term mechanical circulatory assist devices. UpToDate. www.uptodate.com. Published August 31, 2022. Accessed January 3, 2024.
11. Yarlagadda VV, Maeda K, Zhang Y, et al. Temporary Circulatory Support in U.S. Children Awaiting Heart Transplantation. *J Am Coll Cardiol*. 2017;70(18):2250 to 2260. doi:10.1016/j.jacc.2017.08.072
12. Bulic A, Maeda K, Zhang Y, et al. Functional status of United States children supported with a left ventricular assist device at heart transplantation. *J Heart Lung Transplant*. 2017;36(8):890 to 896. doi:10.1016/j.healun.2017.02.024
13. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. 2012;126(22):2648 to 2667. doi:10.1161/CIR.0b013e3182769a54
14. Singh RK, Singh TP. Heart failure in children: management. UpToDate. www.uptodate.com. Updated November 29, 2022. Accessed January 3, 2024.
15. Dipchand AI, Kirk R, Naftel DC, et al. Ventricular Assist Device Support as a Bridge to Transplantation in Pediatric Patients. *J Am Coll Cardiol*. 2018;72(4):402 to 415. doi:10.1016/j.jacc.2018.04.072
16. Caldeira CCB, Machado RC, Caldeira DCB. Implantation of Short-Term and Long-Term Right Ventricular Assist Devices. *Braz J Cardiovasc Surg*. 2017;32(5):435 to 437. doi:10.21470/1678-9741-2017-0021
17. Ni hci T, Boardman HM, Baig K, et al. Mechanical assist devices for acute cardiogenic shock. *Cochrane Database Syst Rev*. 2020;6(6):CD013002. Published 2020 Jun 4. doi:10.1002/14651858.CD013002.pub2
18. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e876-e894. doi:10.1161/CIR.0000000000001062
19. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE) Program. Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program>. Published September 2019. Accessed January 3, 2024.

CLINICAL POLICY

Ventricular Assist Devices

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. 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.

CLINICAL POLICY

Ventricular Assist Devices

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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.