Clinical Policy: Ventricular Assist Devices

Reference Number: WNC.CP.232
Last Review Date: 11/22

Coding Implications
Revision Log

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

Note: 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.

Description[1]

A ventricular assist device (VAD) is surgically attached to one or both intact heart ventricles and used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed. VADs are used as a bridge to a heart transplant, for support of blood circulation post-cardiotomy, or destination therapy.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover a Food and Drug Administration (FDA)-approved Ventricular Assist Device (VAD) when used according to the device-specific, FDA-approved indications. VADs are covered when **all** the following criteria for a given indication are met:

A. Post-cardiotomy:
   1. The beneficiary is in relatively good health other than the cardiovascular problem for which surgery was undertaken;
   2. All appropriate measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, inadequate cardiac rate, dysrhythmias and residual hypothermia;
   3. Cardiac resuscitation employing pharmacologic agents in a systematic fashion has been attempted. The use of the intra-aortic balloon pump (IABP) is recommended prior to VAD assistance, its use may not be appropriate, as in cases of fibrillating heart or peripheral atherosclerosis; **and**
   4. Hemodynamic selection criteria:
      a. Cardiac index (CI) of less than 2.0L/min/m while receiving maximal medical support;
      b. Systolic Blood Pressure less than 90mm Hg;
      c. Pulmonary Capillary Wedge Pressure greater than 18 mm Hg;
      d. Left atrial pressure of 20 mm Hg; **and**
      e. On maximum inotropic volume and support.

B. Bridge to Transplant:
   1. The beneficiary is:
      a. Approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist, **or**
      b. undergoing evaluation to determine candidacy for a cardiac transplant; **and**
   2. At-risk of imminent death from left ventricular failure before donor heart procurement.

NOTE: The use of an FDA-approved biventricular device may be considered as a medically necessary bridge-to-transplantation for a beneficiary with biventricular failure who is currently listed as a candidate for heart transplant.

C. Destination Therapy (**all** criteria must be met):
   1. The device has been FDA approved for Destination Therapy
   2. The beneficiary has chronic end-state heart failure as classified by New York Heart Association (NHYA) class IV (see table below) and is not a candidate for a heart transplant.
   3. The beneficiary has failed to respond to maximum medical management such as:
      a. Beta-blockers or ACE Inhibitors for at least 45 of the last 60 days, **or**
      b. Has been balloon pump dependent for the last 7 days, **or**
      c. Has been IV inotrope dependent for 14 days.
   4. The beneficiary has a left ventricular ejection fraction (LVEF) less than 25%.
   5. The beneficiary demonstrates functional limitations with peak oxygen consumption less than or equal to 14 ml/kg/min. (Note: This criterion may be waived in a beneficiary who is unable to perform exercise stress testing).

II. Percutaneous Left Ventricular Assist Devices

A. WellCare of North Carolina considers a FDA-approved percutaneous left ventricular assist device (pVAD) (e.g., the TandemHeart, Impella, and other FDA approved pVADs, used in accordance with FDA approval) medically necessary for **one** of the following indications:
   1. Providing short-term circulatory support in cardiogenic shock
   2. Bridge to transplant
   3. Acute MI
   4. Ongoing cardiogenic shock that occurs less than 48 hours following acute MI or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional measures
   5. As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk patients:
      a. Persons undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35 %; ***or***
      b. Persons with three vessel disease and ejection fraction less than 30 %

B. WellCare of North Carolina considers pVADs **experimental and investigational** for all other indications because of insufficient evidence in the peer-reviewed literature.

III. Percutaneous Right Ventricular Assist Devices

A. WellCare of North Carolina considers a FDA-approved percutaneous right ventricular assist device (e.g. Impella RP, ProtekDuo, or other pVAD used in accordance with FDA approval) medically necessary for the following indications:
   1. Acute right heart failure or decompensation following LVAD implantation, MI, heart transplant or open heart surgery

New York Heart Association (NYHA) Functional Classification:

Class	Beneficiary Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

IV. WellCare of North Carolina® **shall not** cover a VAD when the beneficiary does not meet the medical necessity criteria listed in Section I **and** for **any** of the following situations:

A. For any off-label indication;
B. Use of a non-FDA approved or cleared ventricular assist device is considered investigational; **or**
C. Other applications of ventricular devices that are considered investigational.
D. Contraindicated in the following conditions:
   1. Chronic irreversible hepatic, renal or respiratory failure;
   2. Systemic infection;
   3. Blood dyscrasia; **or**
   4. Uncorrected aortic insufficiency.

V. WellCare of North Carolina® **shall not** cover a VAD when the beneficiary or caretaker's psychosocial history limits the ability to comply with pre-transplant or post-transplant medical care.

VI. WellCare of North Carolina® **shall not** cover a VAD when the beneficiary or caretaker's failure or refusal to comply would make compliance with the disciplined medical regime improbable.

Limitations[1]

Replacements of the device or a component of the device is considered medically necessary when any of the following criteria are met:

- A change in the physiological condition of the beneficiary, as documented in the medical record, necessitates a different device; or
- A comorbidity is proven to be exacerbated by the current device or component: **or**
- A non-warranty repair of the device or component is imminent; and the cost of the required repair is estimated to be more than the cost of a replacement device or component.

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

HCPCS ®* Codes	Description
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

+ Indicates a code(s) requiring an additional character

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	Postcardiotomy syndrome
Z76.82	Awaiting organ transplant status
Z95.811	Presence of heart assist device

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	04/21	06/21
Reviewed CPT, HCPCS and ICD-10-CM codes.	12/21	02/22
Annual Review	11/22	11/22
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 11C Ventricular Assist Devices. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published January 6, 2020. Accessed October 3, 2022.
2. Japan VAD Council, IMPELLA Committee. "Appropriate Use Guidance for IMPELLA". Council for Clinical Use of Ventricular Assist Device Related Academic Societies, IMPELLA Committee Office. Rev 1 Mar, 2019. https://j-pvad.jp/en/guidance/. Accessed October 3, 2022.
3. Glazier James J, Kaki Amir. The Impella Device: Historical Background, Clinical Applications and Future Directions. *Int J Angiol.* 2019 Jun; 28(2): 118–123. Published online 2018 Dec 20. doi: 10.1055/s-0038-1676369. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6679960/. Accessed October 3, 2022.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue

codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

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.

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