Table of Contents

1.0 Description of the Procedure, Product, or Service

Ventricular assist devices (VADs) represent a method of providing temporary mechanical circulatory support for beneficiaries not expected to survive until a heart becomes available for their transplant. The scarcity of donor organs has led to the development of interim interventions (i.e., mechanical assist devices). A variety of devices have received approval for marketing from the U.S. Food and Drug Administration (FDA), encompassing both biventricular and left ventricular devices, as well as devices that are intended to be used in the hospital setting alone and those that can be used in an outpatient setting. Left ventricular assist devices (LVADs) are most commonly used as a bridge to transplantation. More recently, given the success of LVADs for prolonged periods of time, there has been interest in using LVADs as permanent "destination" therapy for beneficiaries with end-stage heart disease who are not candidates for human heart transplantation due to age or other co-morbidities.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
b. Provider(s) shall verify each Medicaid or NCHC 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.
d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. **Medicaid**
None Apply.

b. **NCHC**
None Apply.

2.2 Special Provisions

2.2.1 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.

b. **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: http://www.ncdhhs.gov/dma/epsdt/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

VADs are only covered for FDA-labeled indications for use.

VADs are covered when **all** of the following criteria for a given indication are met:

a. For ventricular dysfunction following cardiac surgery:

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. While the use of the intra-aortic balloon pump (IABP) is recommended prior to VAD assistance, its use may not always 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. Approval for cardiac transplantation [listed as Status 1 by United Network for Organ Sharing (UNOS) criteria];
2. Imminent risk of dying before donor heart procurement;
3. On Intra-Aortic Balloon Pump (IABP) (if possible); and
4. Hemodynamic selection criteria of the left atrial pressure or pulmonary capillary wedge pressure greater than 20 mm Hg with either;
    A. systolic blood pressure less than 80 mm Hg; or
    B. cardiac index of less than 2.0 L/min/m2.

NOTE: The use of FDA approved Biventricular devices (including total artificial hearts) as a medically necessary bridge to heart transplantation for beneficiaries with biventricular failure who are currently listed as candidates for heart transplant may be considered.

c. Destination Therapy

1. The beneficiary has **either:**
    A. New York Heart Association (NYHA) class IV heart failure for more than 60 days; or
    B. New York Heart Association (NYHA) class III/IV for 28 days and one of the following:
        i. received more than 14 days support with intraaortic balloon pump; or
        ii. is dependent on IV inotropic agents, with 2 failed weaning attempts.

AND

2. The beneficiary has a peak O_2 consumption of less than 14 ml/kg.

AND

3. The beneficiary shall not be a candidate for human heart transplant for one or more of the following reasons:
    A. Age is older than 65 years;
    B. Insulin dependent diabetes mellitus with end-organ damage;

C. Chronic renal failure (serum creatinine of greater than 2.5 mg/dL) for more than 90 days; or
D. Presence of other clinically significant condition(s).

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

VADs are not covered when the beneficiary does not meet the medical necessity criteria listed in **Section 3.0** 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 left ventricular devices that are considered investigational.

Contraindications for a bridge to transplant VAD include conditions that would generally exclude beneficiaries for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; and blood dyscrasia. Due to potential problems with adequate function of the VAD, implantation is also contraindicated in beneficiaries with uncorrected aortic insufficiency.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
   1. No services for long-term care.
   2. No nonemergency medical transportation.
   3. No EPSDT.
   4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

4.3 Psychosocial History

The beneficiary or caretaker's psychosocial history limits the ability to comply with medical care pre and post transplant.

4.4 Medical Compliance

The beneficiary or caretaker's failure or refusal to comply shall make the disciplined medical regime improbable.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2 .1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for ventricular assist devices.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

None Apply.

5.3 Additional Limitations or Requirements

None Apply.

6.0 Providers 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 or NCHC 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 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 DMA'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)..

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
7/1/2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
11/1/11	Throughout	Updated Standard DMA template language
11/1/11	Sections 1.0, 3.1, 3.2, 4.1 and 4.2, 5.1, 5.2, 7.1, Attachment A –C. coding	Policy was updated to include coverage criteria and requirements to meet current community standards of practice
3/1/12	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. International Classification of Diseases, 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.

ICD-10 Code(s)		
02HA0QZ	02HA4QZ	02UA0JZ
02HA0RS	02HA4RS	02UA3JZ
02HA0RZ	02HA4RZ	02UA4JZ
02HA3QZ	02PA0RZ	5A02116
02HA3RS	02PA3RZ	5A02216
02HA3RZ	02PA4RZ	

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.

CPT Code(s)	
33975	33978
33976	33979
33977	33980

Revenue Code(s)
RC279
RC270

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

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

One billing unit is allowed per day.

F. Place of Service

Inpatient Acute Care Hospital.

G. Co-payments

Co-payments are not required for Ventricular Assist Devices.

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at http://www.ncdhhs.gov/dma/plan/sp.pdf.
For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, see: http://www.ncdhhs.gov/dma/fee/