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1.0 Description of the Procedure, Product, or Service

Ventricular assist devices (VADs) represent a method of providing temporary mechanical circulatory support for patients 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. In both systems, the device is surgically placed entirely within the thoracic and abdominal cavity and connected to the power source by a percutaneous drive line. 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 patients with end-stage heart disease who are not candidates for human heart transplantation due to age or other comorbidities.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients shall be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are 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 recipient’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; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient’s caretaker, or the provider.

3.2 Specific Criteria

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 recipient 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:
 - (i.) Cardiac index (CI) of less than 2.0L/min/m while receiving maximal medical support;
 - (ii.) Systolic Blood Pressure less than 90mm Hg;
 - (iii.) Pulmonary Capillary Wedge Pressure greater than 18 mm Hg;
 - (iv.) Left atrial pressure of 20 mm Hg; and
 - (v.) On maximum inotropic volume and support.

b. Bridge to Transplant

- a. Approval for cardiac transplantation [listed as Status 1 by United Network for Organ Sharing (UNOS) criteria];
- b. Imminent risk of dying before donor heart procurement;
- c. On Intra-Aortic Balloon Pump (IABP) (if possible); and
- d. Hemodynamic selection criteria of the left atrial pressure or pulmonary capillary wedge pressure greater than 20 mm Hg with either:
 - (i.) systolic blood pressure less than 80 mm Hg; or
 - (ii.) 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 recipients with biventricular failure who are currently listed as candidates for heart transplant may be considered.

c. Destination Therapy

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

AND
2. The recipient has a peak O₂ consumption of less than 14 ml/kg.

AND
3. The recipient shall not be a candidate for human heart transplant for one or more of the following reasons:

- (i.) Insulin dependent diabetes mellitus with end-organ damage;
- (ii.) Chronic renal failure (serum creatinine of greater than 2.5 mg/dL) for more than 90 days; or
- (iii.) Presence of other clinically significant condition.

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

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

NCHC does not cover VADs when the recipient 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 recipients 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 recipients with uncorrected aortic insufficiency.

4.3 Psychosocial History

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

4.4 Medical Compliance

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

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for ventricular assist devices (VADs).

5.2 Prior Approval Requirements

The provider shall submit to DMA's designee or DMA the following:

- a. A letter of medical necessity; and

- b. all health care records and any other records that support the recipient has met the specific criteria in **Subsection 3.2** of this policy.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 2011

Revision Information:

Date	Section Revised	Change
11/1/11	Throughout	Initial promulgation of new coverage policy

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

Codes covered include:

CPT Code(s)	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
ICD-9 Procedure Code(s)	Description
37.41	Implantation of prosthetic cardiac support device around the heart (Can be either a ventricular support device on surface of heart or cardiac support device)
37.60	Implantation or insertion of biventricular external heart assist system Note: Device (outside the body but connected to heart) with external circulation pump. Ventriculotomy is included; do not code separately.
37.62	Insertion of temporary non-implantable extracorporeal circulatory assist device
37.64	Removal of external heart assist system(s) or device(s)
37.65	Implant of single ventricular (extracorporeal) external heart assist system
37.66	Insertion of implantable heart assist system
37.68	Insertion of percutaneous external heart assist device
Revenue Code(s)	Description
RC279	Medical Surgical Supplies and devices- Other Supply/Devices
RC270	Medical Surgical Supplies and devices -General Classification

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Acute Care Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services

H. Reimbursement

Providers shall bill their usual and customary charges.