

**Table of Contents**

1.0	Description of the Procedure, Product, or Service.....	1
2.0	Eligible Recipients.....	1
2.1	General Provisions.....	1
3.0	When the Procedure, Product, or Service Is Covered.....	1
3.1	General Criteria.....	1
3.2	Specific Criteria.....	1
4.0	When the Procedure, Product, or Service Is Not Covered.....	3
4.1	General Criteria.....	3
4.2	Specific Criteria.....	3
5.0	Requirements for and Limitations on Coverage.....	4
5.1	Prior Approval.....	4
5.2	Prior Approval Requirements.....	4
6.0	Providers Eligible to Bill for the Procedure, Product, or Service.....	4
7.0	Additional Requirements.....	5
7.1	Compliance.....	5
8.0	Policy Implementation/Revision Information.....	5
	Attachment A: Claims-Related Information.....	6
A.	Claim Type.....	6
B.	Diagnosis Codes.....	6
C.	Procedure Code(s).....	6
D.	Modifiers.....	6
E.	Billing Units.....	6
F.	Place of Service.....	6
G.	Co-payments.....	6
H.	Reimbursement.....	6
I.	Billing for Donor Expenses.....	6

## **1.0 Description of the Procedure, Product, or Service**

Heart (cardiac) transplantation is the surgical excision of a heart and the main arteries from a human, brain-dead donor, with subsequent implantation into a recipient who has had his heart surgically removed in a similar manner. The new heart is surgically attached to the major blood vessels which include the pulmonary arteries, pulmonary veins, aorta, and the vena cava.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NC Health Choice (NCHC) recipients must 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**

NCHC covers heart (cardiac) transplantation when it is considered medically necessary because the following medical criteria are met:

- a. Recipients with heart failure with persistent symptoms at rest who require one or more of the following:
  1. continuous infusion of intravenous inotropic agents, or
  2. mechanical ventilatory support, or
  3. mechanical circulatory support.

- b. Recipients with pediatric heart disease with symptoms of heart failure who do not meet the criteria in **Subsection 3.2.a** but who have:
  1. severe limitation of exercise and activity (if measurable, such recipients would have a peak maximum oxygen consumption  $\leq$  less than 50% predicted for age and sex); cardiomyopathies or previously repaired or palliated congenital heart disease and significant growth failure attributable to the heart disease;
  2. near sudden death and/or life-threatening arrhythmias untreatable with medications or an implantable defibrillator;
  3. restrictive cardiomyopathy with reactive pulmonary hypertension;
  4. reactive pulmonary hypertension and potential risk of developing fixed, irreversible elevation of pulmonary vascular resistance that could preclude orthotopic heart transplantation in the future;
  5. anatomical and physiological conditions likely to worsen the natural history of congenital heart disease in infants with a functional single ventricle; or
  6. anatomical and physiological conditions that may lead to consideration for heart transplantation without systemic ventricular dysfunction.
- c. NCHC covers heart (cardiac) transplantation for recipients with end-stage, irreversible, refractory, symptomatic heart disease requiring maximal continuous medical or mechanical support and who have:
  1. a low functional status;
  2. a poor probability of survival; and
  3. one of the following underlying conditions:
    - A. presence of an implanted ventricular assist device;
    - B. refractory cardiogenic shock;
    - C. dependency on intravenous inotropic support to maintain adequate organ perfusion;
    - D. maximal peak venous oxygenation (  $\dot{V}O_2$  )of 11-14 milliliters/kilogram/minute (or 55% of predicted) and major limitation of activities;
    - E. severe ischemia (or recurrent unstable ischemia) consistently limiting routine activity not amenable to bypass surgery or percutaneous coronary intervention;
    - F. recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities; or
    - G. ischemic cardiomyopathy not amenable to medical therapy or revascularization procedures.

- d. Re-transplantation in recipients with chronic rejection, moderate graft vasculopathy or recurrent disease is considered medically necessary when the recipient meets the general criteria outlined above.
- e. The recipient and caregiver are willing and capable of complying with the post transplant treatment plan.

## 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

- a. Coverage is not provided for organs sold rather than donated to the recipient.
- b. NCHC does not cover heart (cardiac) transplantation when any of the following clinical conditions are present:
  - 1. alcoholic cardiomyopathy (unless abstinent for at least 6 months);
  - 2. systemic illness that would limit life expectancy or compromise recovery from cardiac transplantation;
  - 3. diabetes mellitus with evidence of significant end-organ complications, such as retinopathy, neuropathy, nephropathy, and peripheral or cerebrovascular disease;
  - 4. acute severe hemodynamic compromise at the time of transplant, when accompanied by failure of any vital end-organ, because survival is likely to be compromised;
  - 5. severe peripheral vascular disease or cerebrovascular disease;
  - 6. Current, potentially life-threatening malignancy;
  - 7. active infection (except for infection of a ventricular assist device);
  - 8. irreversible hepatic (liver) dysfunction (transaminases twice normal, with associated coagulopathy), irreversible renal (kidney) dysfunction (serum creatinine greater than 2 mg/dl or clearance less than 50 cc/min);
  - 9. chronic bronchitis or chronic obstructive pulmonary disease forced expiratory volume in one second (FEV I) less than 60% predicted or any irreversible lung disease;
  - 10. cachexia, even without major end-organ failure, as survival is significantly less favorable;
  - 11. Human immunodeficiency virus (HIV) positivity

12. morbid obesity indicated by a body mass index (BMI) greater than  $\geq 40$ , or a BMI greater than  $\geq 35$  with comorbid conditions;
  13. absence of documentation of nonsmoking status;
  14. recent substance abuse that will likely impair compliance with post transplant protocols;
  15. Recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care, or
  16. Current recipient/caretaker non-compliance would make compliance with a disciplined medical regimen improbable.
- c. Pulmonary infarction or embolism during the preceding eight weeks is considered a relative contra-indication.
  - d. Heart transplants requiring planned concurrent coronary artery bypass graft surgery, as this is considered experimental.

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval is required for heart (cardiac) transplantation.

All applicable NCHC policies and procedures must be followed in addition to the ones listed in this procedure.

Only those recipients accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior review. Guidelines must be followed for transplant network or consortiums, if available.

### 5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the health care records and any other records that support the recipient has met the specific criteria in **Subsection 3.2**.

## 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.

FDA approved procedures, products, and devices for implantation must be utilized for heart (cardiac) transplantation.

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 recipient's medical record and made available for review upon request.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

### Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."</b>
	Subsection 2.1	Spelled out NC Health Choice
	Subsection 3.2	Updated criteria
	Subsection 3.3	Removed Subsection and moved criteria to Subsection 5.1
	Subsection 4.2	Updated criteria
	Subsection 5.2	Added Prior Approval requirements
	Section 7.0	Updated compliance
	Attachment A	Updated codes and changed "must" to "shall"

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P 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)

CPT Code	Description
33940	Donor cardiectomy (including cold preservation)
33945	Heart transplant, with or without recipient cardiectomy

ICD-9 Code	Description
37.51	Heart transplantation

### 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

Acute Inpatient 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.

### I. Billing for Donor Expenses

Donor expenses are billed on the NCHC recipient's transplant claim using the recipient's NCHC identification number.

NCHC reimburses only for the actual donor's expenses. NCHC does not reimburse for unsuccessful donor searches.

Cadaveric/Deceased Organ Donations:

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a heart transplant if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.