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1.0 Description of the Procedure, Product, or Service

A combined heart-lung transplant is intended to prolong survival and improve function in recipients with endstage cardiopulmonary disease. The technique involves a coordinated triple operative procedure consisting of procurement of a donor heart-lung block, surgical removal of the heart and lungs of the recipient, and implantation of the heart and lungs into the recipient. A heart/lung transplant refers to the transplantation of one or both lungs and heart from a single cadaver donor.

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 human heart/lung transplantation when considered medically necessary for carefully selected recipients with end-stage cardiac and pulmonary disease including one of the following diagnoses:

- a. Irreversible primary pulmonary hypertension with heart failure;
- b. Non-specific severe pulmonary fibrosis
- c. Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
- d. Cystic fibrosis with severe heart failure; Chronic obstructive pulmonary disease with heart failure;
- e. Emphysema with severe heart failure; or
- f. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure. When the Procedure, Product, or Service Is Not Covered

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 heart/lung transplants for recipients with any of the following contraindications:

- a. Emotional problems or recent substance abuse that will likely impair compliance with post transplant protocols;
- b. History of non-compliance with medical management;
- c. Lack of social support that will likely impair compliance with post transplant protocols;
- d. Active, potentially life-threatening, malignancy (except when transplant is done for a cure);
- e. Other major organ system disease or infection including major vascular disease;
- f. Morbid obesity indicated by a body mass index (BMI) greater than 40, or a BMI greater than 35 with comorbid conditions;
- g. Human immunodeficiency virus (HIV) positivity;
- h. Absence of documentation of nonsmoking status.
- i. Organs sold rather than donated to a recipient; or
- j. Artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

4.3 Psychosocial History

Heart-lung transplantation is not covered when the recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care.

4.4 Medical Compliance

Current recipient or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

4.5 Substance Abuse

Heart-lung transplantation is not covered when the recipient has an active substance abuse or, for recipients with a recent history of substance abuse, there is no documentation of the completion of a substance abuse or therapy program plus six months of negative sequential random drug screens.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required heart-lung 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 approval. 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 following:

- a. the prior approval request; and
- b. all health care records and any other records that support the NCHC recipient has met the specific criteria in **Subsections 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 must 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 and Organ Procurement and Transplant Network (OPTN) - approved procedures, products, and devices for implantation must be utilized for heart/lung 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, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
12/1/11	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

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

C. Procedure Code(s)

CPT Code(s)	Description
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33935	Heart –lung transplant with recipient cardiectomy-pneumonectomy

ICD-9 Code	Description
33.6	Combined heart-lung transplantation

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

One unit per day.

F. Place of Service

Acute Inpatient Hospital

G. Co-payments

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

H. Reimbursement

Providers must bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-NCHC donors 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/lung transplant if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.