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1.0 Description of the Procedure, Product, or Service

Single lung transplantation begins with a thoracotomy, which is a surgical procedure where an incision is made to open the chest cavity. After removal of the native lung, the major vessels are anastomosed (connected) to the donor lung and then to the bronchi. The bronchi are the larger air passages of the lungs.

There are two main techniques for double lung transplantation. The earlier method involved a median sternotomy and removing the lungs as a whole and then connecting them at the trachea. The trachea is also known as the windpipe and is a tube of cartilage lined with mucous membrane passing from the larynx to the bronchi of the lungs. The more recent method uses a transverse (diagonal) thoracotomy with separate transplantation of each lung with bilateral airway anastomoses or connections to the donor lung at the bronchi.

In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions, and transplanted. Donors for lobar transplants have been primarily living-related donors, with one lobe obtained from each of two donors (e.g., mother and father) in cases where a bilateral transplant is required. There are also cases of cadaver lobe transplants.

These lung transplantations are intended to prolong survival and improve function in recipients with severe pulmonary disease.

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 lung or lobar lung transplantation when:

- a. Medically necessary for carefully selected NCHC recipients with irreversible, progressively disabling, end-stage pulmonary disease including one of the conditions listed below:
 1. Debilitating lung disease (functional status of the New York Heart Association Class III after maximal rehabilitation) including:
 - A. Idiopathic or Interstitial pulmonary fibrosis - with significant impairment of forced vital capacity(FVC)(e.g. FVC less than 65% of predicted);
 - B. Cystic fibrosis (both lungs to be transplanted) - with severe impairment of FVC (e.g. less than 40% of predicted), forced expiratory volume in one second (FEV1) (e.g. less than 30% of predicted), and room air partial pressure of oxygen(PaO₂) (e.g. less than 60 mmHg). In NCHC recipients with cystic fibrosis there are no absolute contraindications based on either the type of the organism or the pattern of resistance;
 - C. Primary pulmonary hypertension;
 - D. Emphysema - the FEV1 post bronchodilator less than 25% predicted;
 - E. Bilateral bronchiectasis;
 - F. Alpha-1 antitrypsin deficiency;
 - G. Bronchopulmonary dysplasia;
 - H. Sarcoidosis;
 - I. Scleroderma;
 - J. Lymphangiomyomatosis;
 - K. Eosinophilic granuloma;
 - L. Bronchiolitis obliterans;
 - M. Recurrent pulmonary embolism;
 - N. Pulmonary hypertension due to cardiac disease;
 - O. Eisenmenger's syndrome; or
 - P. Chronic Obstructive Pulmonary Disease.
- b. The recipient and caregiver are willing and capable of complying with the post transplant treatment plan;
- c. The recipient has adequate cardiac status; and
- d. The recipient is human immunodeficiency virus(HIV)-positive, or has acquired immunodeficiency syndrome(AIDS), the case shall be evaluated on an individual basis providing the following criteria are present:
 1. Cluster of differentiation(CD4) count >200 cells/mm³ for more than 6 months;
 2. HIV-1 Ribonucleic Acid (RNA) undetectable;
 3. On stable anti-retroviral therapy for more than 3 months;
 4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
 5. Meeting all other criteria for transplantation.

Note: For all NCHC recipients, including those with end-stage lung disease and HIV infection, evaluation of a candidate for transplant needs to consider the probability of a successful transplant and the limited supply of organs available.

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

Lung or lobar lung transplantation is not covered when a NCHC recipient has **any one** of the contraindications listed below:

- a. General contraindications:
 1. Active drug or alcohol abuse, or tobacco use within the last six months;
 2. Obesity (over 20-30% over ideal body weight) at time of transplant;
 3. Contraindication to immunosuppressive drugs;
 4. Multiple uncorrectable congenital abnormalities that significantly affect quality and duration of life (such as anencephaly or other severe congenital anomalies).
- b. Contraindications related to infections:
 1. Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B or C;
 2. Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria is a relative contraindication to be included in a comprehensive evaluation of all other comorbidities.
- c. Contraindications related to other diseases:
 1. Current, potentially life-threatening, malignancy;
 2. Bone marrow failure (any cell line);
 3. Severe congenital immunodeficiency;
 4. Significant or advanced other disease including:
 - A. Hepatic dysfunction, including cirrhosis and chronic liver disease;
 - B. Renal dysfunction (creatinine over 1.5 or creatinine clearance less than 50 ml/min or less than 35 ml/min for pulmonary hypertension recipients);
 - C. Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function (however, heart-lung transplantation could be considered in highly selected cases).
 6. Other systemic disease that impairs function or expected duration of life;
 7. Cerebral dysfunction, such as severe impairments which affect quality of life and ability to comply with transplant regimen;
 8. Behavioral or psychiatric disorder considered likely to compromise adherence with strict medical regimen and follow-up after transplant, including physical rehabilitation.
- d. Emotional problems or recent substance abuse (including smoking);
- e. History of non-compliance with medical management; or
- f. Absence of a consistent or reliable social support system.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval (PA) is required for lung or lobar lung transplantation. A living donor shall require prior approval.

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

Only those NCHC 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 and Organ Procurement and Transplant Network (OPTN) - approved procedures, products, and devices for implantation must be utilized for lung or lobar 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 and OPTN 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
		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
	Throughout	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-1

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
32850	Donor pneumonectomy(s) (including cold preservation) from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc);with cardiopulmonary bypass

ICD-9 Code	Description
33.50	Lung transplantation, NOS
33.51	Unilateral lung transplantation
33.52	Bilateral lung 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 for non-NCHC donors are billed on the recipient's transplant claim. Donor expenses for NCHC donors are billed on the donor's claim.

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 lung or lobar lung transplant if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.

Living Organ Donations

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a lung or lobar lung transplant if the transplant recipient has received prior approval for a living organ transplant procedure. NCHC covers reimbursement only for the approved donor.