To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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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 beneficiary'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 beneficiaries with severe pulmonary disease.

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 policies*)

a. An eligible beneficiary shall be enrolled in
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*);

b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

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

a. Medicaid

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: https://medicaid.ncdhhs.gov/

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 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 Medicaid

Medicaid shall cover lung or lobar lung transplantation when the beneficiary meets the following criteria:

a. Medically necessary for carefully selected beneficiaries 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 (PaO_2) (e.g. less than 60 mmHg). In beneficiaries 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 beneficiary and caregiver are willing and capable of complying with the post transplant treatment plan;
c. The beneficiary has adequate cardiac status; and
d. The beneficiary 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 greater than 200 cells/mm-3 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, coccidioses mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
   5. Meeting all other criteria for transplantation.

Note: For all Medicaid beneficiaries, 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.

3.2.2 Medicaid 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 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 Medicaid

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

a. General contraindications:
   1. Active drug or alcohol use, or tobacco use within the last six months;
   2. Obesity (more than 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 beneficiaries);
      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).
   5. Other systemic disease that impairs function or expected duration of life;
   6. Cerebral dysfunction, such as severe impairments which affect quality of life and ability to comply with transplant regimen;
   7. Behavioral or psychiatric disorder considered likely to compromise adherence with strict medical regimen and follow-up after transplant, including physical rehabilitation.

d. Advanced physiologic age;
e. Emotional problems or recent substance use (including smoking);
f. History of non-compliance with medical management; or
g. Absence of a consistent or reliable social support system.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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 shall not require prior approval for lung or lobar lung transplantation.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

6.0 Provider(s) 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 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 NC Medicaid'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 and Organ Procurement and Transplant Network (OPTN) - approved procedures, products, and devices for implantation must be utilized for lung or lobar lung transplantation.

A statement signed by the surgeon certifying all FDA and OPTN 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, 1990

Revision Information:

Date	Section Revised	Change
07/01/2005	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
02/01/2006	Section 3.4.4	Pulmonary infiltrates without hilar adenopathy and non-pulmonary features were deleted as coverage criteria for sarcoidosis; the criteria for total lung capacity was revised to <70%.
12/01/2006	Sections 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
05/01/2007	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
05/01/2007	Attachment A	Added the UB-04 as an accepted claims form.
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
12/01/2011	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
03/12/2012	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-1 under Session Law 2011-145, § 10.41.(b)
03/12/2012	Attachment A	Removed the UB-04 claim form from A.
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2012	Subsection 5.3	Prior authorization requirements for recipients with ETOH/substance abuse issues was added.
08/01/2012	Throughout	Replaced "recipient" with "beneficiary."
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.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/06/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after

Date	Section Revised	Change
		implementation, please contact your PHP."
01/06/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
07/01/2021	Section 5.0	Prior approval requirement removed.
07/01/2021	Attachment A	Added claim type Institutional (UB-04/83711). Removed specific ICD-10 PCS and CPT codes. Removed prior approval language from Section I.
8/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 8/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

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

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/83711)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, 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.

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.

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

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

One unit per day.

F. Place of Service

Acute inpatient hospital.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

I. Billing for Donor Expenses

1. **Billing for Donor Expenses for Medicaid Beneficiaries**
   Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number.

   Medicaid reimburses only for the actual donor's transplant-related medical expenses. Medicaid does not reimburse for unsuccessful donor searches.

2. **Cadaveric/Deceased Organ Donations**
   Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a lung or lobar lung transplant.

3. **Living Organ Donations**
   Donor transplant-related medical expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a lung or lobar lung transplant. Medicaid covers reimbursement only for the approved donor.