

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1

2.0 Eligible Recipients 1

 2.1 General Provisions 1

 2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age 1

3.0 When the Procedure, Product, or Service Is Covered..... 2

 3.1 General Criteria..... 2

 3.2 Specific Criteria 3

4.0 Procedure, Product, or Service Is Not Covered 4

 4.1 General Criteria..... 4

 4.2 Specific Criteria 4

5.0 Requirements for and Limitations on Coverage 5

 5.1 Prior Approval 5

 5.2 Prior Approval Requirements 5

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 6

7.0 Additional Requirements 6

 7.1 Compliance 6

8.0 Policy Implementation/Revision Information..... 7

Attachment A: Claims-Related Information 8

 A. Claim Type 8

 B. Diagnosis Codes 8

 C. Procedure Code(s)..... 8

 D. Modifiers..... 8

 E. Billing Units..... 8

 F. Place of Service 8

 G. Co-payments 8

 H. Reimbursement 8

 I. Billing for Donor Expenses 9

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

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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/or 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 will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

3.0 When the Procedure, Product, or Service Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

3.1 General Criteria

Medicaid 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 statewide; 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

Medicaid covers lung or lobar lung transplantation when:

- a. Medically necessary for carefully selected Medicaid 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 Medicaid 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 greater than 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 Medicaid 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 Procedure, Product, or Service Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

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, investigational, or part of a clinical trial.

4.2 Specific Criteria

Lung or lobar lung transplantation is not covered when a Medicaid 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~~ 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 Medicaid 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).
- 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 abuse (including smoking);
- f. History of non-compliance with medical management; or
- g. Absence of a consistent or reliable social support system.

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

5.1 Prior Approval

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

Only those Medicaid 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.

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

5.2 Prior Approval Requirements

Refer to *Basic Medicaid Billing Guide*, Section 6 at <http://www.ncdhhs.gov/dma/basicmed/>

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 Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; 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

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

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: January 1, 1990

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
2/1/06	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%.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
	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 Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

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)

Codes covered include:

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

One unit per day.

F. Place of Service

Acute inpatient hospital

G. Co-payments

Co-payments are required for lung or lobar lung transplantation

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

Medicaid reimburses only for the actual donor's expenses. Medicaid 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/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/lobar lung transplant if the transplant recipient has received prior approval for a living organ transplant procedure. Medicaid covers reimbursement only for the approved donor.