Clinical Policy: Lung Transplantation

Reference Number: WNC.CP.249
Last Review Date: 02/2025

Coding Implications
Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

This policy describes the medical necessity criteria for Lung Transplantation.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover lung or lobar lung transplantation when the Member meets the following criteria:

A. Medically necessary for carefully selected members 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 members 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 Member and caregiver are willing and capable of complying with the post-transplant treatment plan;

C. The Member has adequate cardiac status; **and**
D. The Member 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, coccidiosis mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); **and**
5. Meeting all other criteria for transplantation.

***Note**: For all members, 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.*

II. Lung or lobar lung transplantation is **not covered** by WellCare of North Carolina® when a Member 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 members);
   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.

Background[1]

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 Member'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 lobar transplants.

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

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	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

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	05/21	05/21
Reviewed CPT codes.	04/22	05/22
Annual Review. NCHC verbiage removed from NC Guidance verbiage.	05/23	05/23
Annual review. ICD-10-CM code and HCPCS tables removed.	02/24	02/24
Annual Review. Removed "Medicaid and health choice" verbiage from References.	02/25	02/25

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 11B-1 Lung Transplantation. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published August 15, 2023. Accessed November 5, 2024.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in 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.

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.

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/

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.

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).

Claims-Related Information

Provider(s) shall comply with the NC Tracks 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 - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   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 - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

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

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.