



CLINICAL POLICY AND PROCEDURE MANUAL

Policy Number: PA.007.CC
Last Review Date: 05/16/2024
Effective Date: 06/01/2024

PA.007.CC Transplant: Lung and Lobar Lung

Summary

A list of medical conditions treated by lung transplantation may include:

- Pulmonary vascular disease:
 - Primary pulmonary hypertension
 - Eisenmenger's syndrome or complex
 - Pulmonary hypertension secondary to thromboembolic disease
 - Cardiomyopathy with pulmonary hypertension
- Obstructive lung disease:
 - Emphysema – idiopathic
 - Emphysema – alpha (1) antitrypsin deficiency
 - Cystic Fibrosis
 - Bronchiectasis
 - Chronic Obstructive Pulmonary Disease (COPD)
- Restrictive lung disease:
 - Idiopathic pulmonary fibrosis
 - Interstitial pulmonary fibrosis
 - Sarcoidosis
 - Asbestosis
- Subsequent operation for failure of original graft

According to UNOS, the overall median waiting time in 2012 was four months, and 65.3% of candidates underwent transplant within one year of listing. There were over 1,700 lung transplants were conducted in 2012 and UNOS estimates that at that time, there were more than 10,000 recipients alive with a lung transplant.

Body mass index, airflow obstruction, Dyspnea and Exercise Capacity (BODE) Index for COPD Survival Prediction

- FEV1 % Predicted After Bronchodialator
 - $\geq 65\%$ (0 points)
 - 50-64% (1 point)
 - 36-49% (2 points)
 - $\leq 35\%$ (3 points)



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- 6 Minute Walk Distance
 - \geq 350 Meters (0 points)
 - 250-349 Meters (1 point)
 - 150-249 Meters (2 points)
 - \leq 149 Meters (3 points)
- Modified Medical Research Council Scale (MMRC) Dyspnea Scale
 - MMRC 0: Dyspneic on strenuous exercise (0 points)
 - MMRC 1: Dyspneic on walking a slight hill (0 points)
 - MMRC 2: Dyspneic on walking level ground; must stop occasionally due to breathlessness (1 point)
 - MMRC 3: Must stop for breathlessness after walking 100 yards or after a few minutes (2 points)
 - MMRC 4: Cannot leave house; breathless on dressing/undressing (3 points)
- Body Mass Index
 - >21 (0 points)
 - ≤ 21 (1 point)

Approximate 4 Year Survival Interpretation:

0-2 Points: 80%, 3-4 Points: 67%, 5-6 points: 57%, 7-10 points: 18%

New York Heart Association (NYHA) Functional Classification:

- I. No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
- II. Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
- III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
- IV. Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Clinical Criteria

County Care considers **Lung and Lobar Lung Transplants** medically necessary for the following indications:

Recipient Characteristics

- The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens

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- The member has no unaddressed barriers to ability to comply with immunosuppression protocol and follow-up requirements and no active alcohol, tobacco, or illicit substance misuse
- The member must have an adequate family and social support system in place

GENERAL CRITERIA for Lung and Lobar Lung Transplant

1. The member meets the institution's selection criteria for lung or lung lobar transplantation.
2. Lung-lobar lung transplantation is indicated for patients with chronic, progressive, and disabling end-stage lung disease and all of the following:
 - Who are failing maximum evidence-based medical therapy, or for whom no medical therapy exists,
 - Who demonstrate adequate health behaviors, the willingness and ability to adhere to complex post-transplant medical regimens and follow-up with health care professionals,
 - Who meet all of the disease-specific criteria and do not have any of the limitations or contraindications listed in this policy.

DISEASE SPECIFIC CRITERIA:

Idiopathic pulmonary fibrosis or Usual Interstitial Pneumonia (UIP) - UIP is more common, more serious and associated with more rapid decline than non-specific interstitial pneumonias or pulmonary fibrosis associated with connective tissue diseases. Indications include any of the following:

- a) Diffusion lung capacity for carbon monoxide (DLCO) < 39% predicted
- b) A 10% or greater decrease in forced vital capacity (FVC) during a six (6) month period
- c) A decrease in pulse oximetry below 88% during a six (6)-minute walk test
- d) Honeycombing on high-resolution CT scan with a fibrosis score > 2

Nonspecific interstitial pneumonia (NSIP) confirmed with histologic analysis and any of the following:

- a) Diffusion lung capacity for carbon monoxide < 35% predicted
- b) A 10% or greater decrease in FVC or 15% decrease DLCO during a six (6) month follow-up period

Pulmonary fibrosis associated with collagen vascular diseases:

- Current data do not support specific criteria for lung transplantation
- FVC < 70-80% predicted at the time of or within five years of diagnosis is predictive of decreased survival and end-stage lung disease

Sarcoidosis:

- NYHA Class III or IV symptoms and any of the following:
 - a) Hypoxemia at rest
 - b) Pulmonary hypertension
 - c) Elevated right atrial pressure exceeding 15 mmHg

Obstructive lung diseases (e.g., COPD):

- Patients with a BODE index of 7-10 or at least one of the following:
 - a) History of hospitalization(s) within the past year for exacerbation associated with hypercapnea and $pCO_2 > 50\text{mmHg}$
 - b) Refractory cor pulmonale and/or pulmonary hypertension despite oxygen therapy
 - c) FEV1 < 20% predicted and DLCO < 20% predicted or homogenous distribution of emphysema

Pulmonary arterial hypertension:

- Persistent NYHA Class III or IV symptoms on maximal medical therapy
- Low (less than 350 m) or declining six (6) minute walk test
- Failing therapy with IV epoprostenol, or equivalent
- Cardiac Index of less than 2 liters/min/m²
- Right atrial pressure exceeding 15 mmHg

Cystic Fibrosis and other causes of Bronchiectasis:

- Any of the following:
 - a) FEV1 < 30% predicted or a rapidly declining lung function if FEV1 >30% (especially in young female patients)
 - b) Exacerbation of pulmonary disease requiring ICU stay
 - c) Increased frequency of exacerbations requiring antibiotic therapy
 - d) Refractory and/or recurrent pneumothorax
 - e) Recurrent hemoptysis not controlled by embolization
- And all of the following:
 1. Oxygen-dependent respiratory failure

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2. Hypercapnea
3. Pulmonary hypertension

Specific Criteria for Lung and Lobar Lung Transplant in HIV+ Members

Lung-lobar lung transplantation in HIV+ members is considered medically necessary when all of the following conditions are met:

1. The member has a life expectancy of at least five years,
2. CD4 count ≥ 200 cells/mL for at least six (6) months,
3. Undetectable HIV viremia (< 50 copies/mL) for six (6) months,
4. Demonstrated adherence to highly active antiretroviral therapy (HAART) regimen for \geq six months,
5. Available antiretroviral treatment options post-transplant

Limitations

1. All other medical and surgical therapies that might be expected to yield both short- and long-term survival comparable to that of transplantation must have been tried or considered.
2. Members must first undergo stringent physical and psychological evaluation to determine eligibility for transplant. Members should have no other serious medical problems, and they should be psychologically willing to undergo the stressful surgery and postoperative care necessary.
3. Living Donors for lobar lung transplantation must be capable of giving informed consent, have no cardiopulmonary abnormalities or history of thoracic surgery on the donor lung side, and must be currently a nonsmoker for six months. Transplant centers must ensure that the prospective donor has been informed regarding the aspects of living donation and possible outcomes.
4. Xenotransplants of lung or lobar lung for any condition is considered experimental and investigational (e.g., porcine xenografts).
5. Chronic high-dose steroid therapy due to impairment of bronchial healing.

Absolute contraindications for adults and children include, but may not be limited to:

- Age appropriateness
- 65 years of age for single lung (must be evaluated before 63rd birthday)
- 65 years of age for double lung transplant
- 55 years of age for heart/lung transplant
- Active smoker (less than 6 months since quitting)
- Active substance abuse

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- Chronic mechanical ventilation (unless tolerating 3 hours of physical therapy/day and is free of bacterial colonization)
- Previous lung transplant (rare exceptions for Johns Hopkins Hospital primary transplant patients)
- Severe Diffuse Coronary artery disease (especially with poor EF)
- End-stage renal disease (creatinine clearance < 40 mg/min)
- End-stage liver disease
- Bone marrow dysfunction
- HIV
- Severe local or systemic infection
- Severe neurologic deficits
- Untreatable psychiatric

Relative contraindications for adults and children include, but may not be limited to:

- Morbid obesity (BMI>30)
- Severe malnutrition/cachexia
- Chronic prednisone use > 20 mg / day
- Symptomatic osteoporosis
- Psychiatric / social problems (including non-compliance)
- Financial problems (no prescription coverage)
- Previous thoracic surgery / procedure
- Lack of family or social support
- Cancer in the last 5 years except localized skin (never melanoma)
- Colonization with resistant organisms

The criteria applies to the following procedure codes:

Code Type	Code	Description
CPT	32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
CPT	32851	Lung transplant, single
CPT	32852	Lung transplant, single; with bypass
CPT	32853	Lung transplant, double
CPT	32854	Lung transplant, double; with bypass
CPT	32855	Backbench preparation of cadaver donor lung; unilateral
CPT	32856	Backbench preparation of cadaver donor lung; bilateral
HCPCS	S2060	Lobar lung transplant

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HCPCS	S2061	Donor lobectomy (lung) for transplantation, living donor
HCPCS	S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and posttransplant care in the global definition

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Revision History

Revision	Date
Created Policy	09/27/2022
Updated Evolent Logo, Replaced invalid link in Reference #1; updated "Last Review Date" in Reference #2; updated "Revised" Date in Reference #3; updated "Page Last Updated Date" in Reference #9; format update to Reference #s 10, 11 and 23; updated date in Reference #15; Replaced Reference #25	09/14/2023
Updated Last Reviewed date in Reference #2; minor punctuation update to Reference	05/16/2024

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#3; updated Up to Date Date and added Last Updated Date to Reference #15; Updated citation and replaced invalid link in Reference 17; format update to Reference #25	
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