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MEDICAL POLICY



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Medical Policy Title	Lung and Lobar Lung Transplant
Policy Number	7.02.10
Current Effective Date	May 22, 2025
Next Review Date	May 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

POLICY STATEMENT(S)

- I. Lung transplantation is **medically appropriate** for carefully selected candidates who have irreversible, progressively disabling, end-stage pulmonary disease and who meet **ALL** of the following criteria:
 - A. Adequate cardiac status;
 - B. Absence of infection, or absence of extrapulmonary infection in individuals with cystic fibrosis;
 - C. No history of malignancy within five (5) years of transplantation, excluding nonmelanomatous skin cancers; **and**
 - D. Documentation of compliance with medical management.
- II. Indications for a lung transplantation include, but are not limited to the following:
 - A. Bilateral bronchiectasis;
 - B. Congenital bronchiectasis;
 - C. Alpha-1 antitrypsin deficiency;
 - D. Primary pulmonary hypertension;
 - E. Cystic fibrosis;
 - F. Bronchopulmonary dysplasia;
 - G. Idiopathic pulmonary fibrosis;
 - H. Interstitial pulmonary fibrosis;
 - I. Sarcoidosis;
 - J. Scleroderma;
 - K. Lymphangiomyomatosis;
 - L. Emphysema;
 - M. Eosinophilic granuloma;
 - N. Bronchiolitis obliterans;
 - O. Recurrent pulmonary embolism;

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- P. Chronic obstructive pulmonary disease (COPD);
- Q. Tuberculous fibrosis of lung;
- R. Pneumoconiosis and other lung diseases due to external agents;
- S. Eisenmenger's syndrome.
- III. Lung transplant is considered a contraindication in human immunodeficiency virus (HIV) positive individuals, unless **ALL** the following criteria are met.:
 - A. CD4 count greater than 200 cells/mm³;
 - B. Undetectable HIV-1 ribonucleic acid (RNA);
 - C. On stable anti-retroviral therapy for greater than three (3) months; and
 - D. All other criteria for transplantation within this policy are met.

RELATED POLICIES

Corporate Medical Policy

7.02.06 Heart & Heart/Lung Transplant

POLICY GUIDELINE(S)

- I. Prior authorization requirements are contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.
- II. Recipient Selection Guidelines

Each recipient considered for transplantation should have an evaluation completed by the transplant center, for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

The following general medical conditions can have an impact on the long-term outcome of lung transplant recipients. Other medical conditions, when they have not resulted in organ damage, are generally acceptable in candidates for lung transplantation (e.g., systemic hypertension, diabetes mellitus, peptic ulcer disease) and should be optimally treated and well-controlled. In the presence of any comorbid medical condition with the potential for end-organ damage, a careful search should be made for evidence of organ dysfunction.

Current use of corticosteroids is not a contraindication to transplantation. However, all attempts to discontinue these drugs or at least reduce the dose to less than or equal to 20 mg per day of prednisolone or prednisone should be made.

Nutritional issues are important predictors of surgical outcome. Individuals with an ideal body weight less than 70% or greater than 130% require either weight gain or weight loss to become eligible for transplant.

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Substance abuse issues need to

Substance abuse issues need to be addressed prior to lung transplantation. Candidates must have been free of substance addiction (e.g., alcohol, tobacco, narcotics) for at least six months. Appropriate preoperative biochemical monitoring is recommended in at-risk individuals.

Psychosocial problems that are unable to be resolved and that have a high likelihood of having a negative impact on the individual's outcome (e.g., poorly controlled major psycho-affective disorder, inability to comply with complex medication regimen) are a relative contraindication. A documented history of noncompliance with medical care or treatment plans, even in the absence of a documented psychiatric condition, is a relative contraindication.

Colonization with fungi or atypical mycobacteria is not an absolute contraindication to transplantation. Cases should be considered on an individual basis. Special care should be taken when a unilateral transplant is considered. When possible, pre-operative attempts to eradicate colonization with antibiotic therapy are appropriate. Adequately treated mycobacterium (M) tuberculosis is not a contraindication to lung transplantation.

- III. Pre-transplant evaluation documentation should include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):
 - A. <u>Clinical Evaluation</u>
 - 1. Confirmation of diagnosis;
 - 2. Identification of comorbidities;
 - 3. Treatment of co-morbidities;
 - 4. Current assessment of co-morbidities; and
 - 5. Consult notes (if applicable).
 - B. Psycho-Social Evaluation
 - 1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score.
 - 2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or substance abuse).
 - C. Oral Health Evaluation
 - D. Lab Tests
 - 1. CBC, metabolic profile;
 - 2. Serologies: CMV; Hepatitis B and C; and
 - 3. HIV Testing.
 - E. Cardiac Assessment
 - 1. 12 Lead EKG; and
 - 2. Stress (exercise, nuclear, or dobutamine), and

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- 3. Echo or MUGA Scan
- F. Pulmonary Assessment
 - 1. Chest x-ray;
 - 2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and
 - 3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking).
- G. Age-appropriate Screening Tests:
 - Please refer to the U.S. Preventive Services Task Force (USPSTF) [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Apr 21]. Available from: <u>https://uspreventiveservicestaskforce.org/uspstf/</u>
- IV. Transplant reauthorization is required annually while on the transplant waiting list, using the same criteria as pre-testing requirements (See Policy Guideline III). If the individual health condition remains unchanged from the previous year, some testing may be waived. If testing is not performed, a rationale must be provided, and documentation must be dated within the last 11 months, unless otherwise specified (e.g., age-related testing).

DESCRIPTION

The lungs are paired organs that consist of the right and left lung, each with different anatomical features and functions. Anatomically the right lung is divided into three lobes, the upper, middle, and lower lobe. In contrast the left lung consists of two lobes, the upper and lower lobes. A lung (sometime called lobar) transplant is a surgical procedure in which a diseased or damaged lung is replaced with a healthy lung from a donor. Lungs that are suitable for transplantation are typically harvested from either brain-dead donors or after the declaration of circulatory death. There's also the option of living donor lobar lung transplantation (LDLLT). LDLLT involves two healthy donors. The right and left lower lobes are retrieved from two healthy donors and are implanted into a single recipient. This procedure is primarily used for individuals who would not survive being on the wait list for a cadaver donor lung. Lung transplantation offers carefully selected individuals the only curative treatment for those individuals with advanced lung disease of various nonmalignant etiologies.

There are three main types of lung transplant. A single lung transplant consists of one diseased or damaged lungs being removed and replaced with a donated lung. A double lung transplant consists of both lungs being removed and replace with donated lungs. The third type of lung transplant is a heart to lung transplant which consists of a heart and both lungs being removed and replaced with a donared both lungs being removed and replaced with a donated lung.

Lung transplants can be performed on individuals of almost all ages from newborns to adults up to the age 65 and in certain cases over the aged 65. The indications for a lung transplant differ for adults and children. Cystic fibrosis and pulmonary arterial hypertension (PAH) have historically

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contributed to many young adult's lung transplant. In adults the primary indication for a lung transplant is chronic obstructive pulmonary disease (COPD) accounting for 40% of all lung transplantations perform worldwide (Kumar et al., 2024). Interstitial lung disease, pulmonary vascular disease, bronchiectasis, and sarcoidosis were the other most common indications for adult lung transplants.

Lung transplantation is a major operation with significant surgical risk and a median post-transplant survival of 5.7 years (Ruck et al.,2025). Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long-term survival.

A shortage of lung donors remains a major limiting factor to the number of transplants performed. These disparities are likely due to the vulnerability of potential complications that occurred before and after brain death which can include thoracic trauma, aspiration, ventilator associated injuries, pneumonia, and neurogenic pulmonary edema. The lung allocation score (LAS) help prioritize individuals and improve outcomes. The LAS comprised of 12 physiological and demographic factors that influence mortality in individuals with advanced lung disease. LAS is determined by subtracting the predictive one-year survival without transplant from the predicted one-year survival with transplant then normalizing the score to a range of 0 to 100. Organs are allocated to individual with the highest score before those with lower scores.

SUPPORTIVE LITERATURE

The International Society for Heart and Lung Transplantation (ISHLT) and the Organ Procurement Transplantation Network (OPTN) data registry suggest that inferior outcomes occur in adolescent lung transplant recipients. The reasons for these inferior outcomes remain undefined and they happen despite the adolescent recipients young age and recipients lack comorbidities. Paraskeva et al. (2018) analyzed survival rates of adolescent lung transplant recipients using data from the ISHLT registry that consisted of recipients between the ages of 0 and 65 years who underwent 24,730 lung transplant procedures. Individuals between 10 and 24 years old at the time of transplant represented 9% of the registry cohort (n=2319), and they were compared with both old and young cohorts. Most adolescents (88%) were transplanted in middle to late adolescence, aged 15-24 years. The overall survival in the adolescent cohort was 65% at three years, which were like those observed in adults between 50 and 65 years of age, and significantly lower in comparison to the pediatric subgroup (73%; p=.006), and adults 25 to 34 years old (75%; p<.001) and 35 to 49 years old (71%; p<.001). The adolescent group individuals between 15 and 19 years of age had the worst survival rates at 3 years (59%) compared with 10- to 14-year-old individual (73%; p<.001) and 20- to 24-year-old year individual (66%; p<.001). Cystic fibrosis (CF) was the main indication for transplantation in adolescent recipients (75% vs 13%; p o 0.001), whereas most adults was transplanted for emphysema and interstitial lung disease (ILD). Compared with the adult groups, more females were transplanted in adolescence. The registry study was biased towards including North American data and may contain potential data entry errors, or missing information. Additionally, there were no data reported on the differences in causes of mortality or the rates of graft dysfunction between the groups.

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Mansour et al. (2023) conducted a systematic review and meta-analysis comparing single lung transplant (SLT) versus bilateral lung transplant (BLT) for managing end stage chronic obstructive pulmonary disease. The study analyzed data from seven studies including 10,652 individuals and found that BLT is associated with more favorable survival rates than SLT. Subgroup analysis on survival rates of alpha-1 antitrypsin deficiency also displayed a trend favoring BLT compared with SLT at 1 year. However, the group had significant heterogeneity in baseline characteristics. The study also found that BLT recipients tend to have longer hospital stays and greater number of acute rejection events while SLT recipients tend to experience more postoperative complications. The authors concluded that BLT may be more effective approach for managing COPD, but further prospective studies are needed to confirm these findings.

Lung volume reduction (LVR) and lung transplantation (LTx) are management options for end stage COPD. Ahmad et al. (2023) compared the outcomes of LVR and LTx in COPD individuals by pooling existing evidence. A meta-analysis of prospective studies on LVR and LTx published since 2000 was conducted. Baseline characteristics, perioperative variables, and clinical outcomes analysis was extracted. The analysis included 65 prospective studies comprising of 3,671 individuals. Mean age was 60 (95% confidence interval (CI): 58-62) years and comparable between the two groups. Females were 51% (95% CI: 30-71%) in the LTx group versus 28% (95% CI: 21-36%) in LVR group. Baseline 6-minute walk test (6MWT) and pulmonary function tests (PFT) were comparable except for the forced expiratory volume in 1 second (FEV1), which was lower in the LTx group (21.8% (95% CI: 16.8-26.7%) versus 27.3% (95% CI: 25.5-29.2%). Postoperatively, both groups experienced improved FEV1. However, LTx resulted in significantly higher FEV1 postoperatively (54.9% (95% CI: 41.4-68.4%) *versus.* 32.5% (95% CI: 30.1-34.8%), but otherwise had comparable outcomes to LVR. Overall, there was no significant difference between the groups. Pooled survival overtime showed no significant difference. LTx led to greater improvement in FEV1 but had comparable outcomes to LVR.

Veno-arterial extracorporeal membrane oxygenation (V-A ECMO) has become increasingly popular for interoperative support during lung transplants even in uncomplicated cases. Pettenzuzzo et al. (2024) conducted a systematic review and meta-analysis of the efficacy and safety of (V-A ECMO) and cardiopulmonary bypass (CBP) compared to an OffPump strategy during lung transplant. The main outcomes assessed were intraoperative red blood cell (RBC) transfusion (units), fresh frozen plasma (FFP) transfusion (units), platelet (PLT) transfusion (units), postoperative invasive mechanical ventilation (IMV duration (days), intensive care unit (ICU) length of stay (LOS days)), ECMO support, and mortality (within the first 90 days after ICU admission). There were 27 observational studies with 6113 individuals included. V-A ECMO and CPB were associated with higher blood product consumption, longer IMV duration, prolonged ICU length of stays, longer surgical duration, and higher mortalities compared to off pump surgeries. VA ECMO overperformed CPB in nearly all other outcomes except for RBC transfusion. Older age, male gender, and body mass index >25kg/m2 negatively impacted several outcomes (RBC transfusion, ICU LOS, surgical duration, need of postoperative ECMO and mortality), regardless of the intraoperative extracorporeal support investigated. Researchers suggested that future studies are necessary to optimize and standardize the intraoperative management of lung transplants.

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PROFESSIONAL GUIDELINE(S)

Idiopathic Pulmonary Fibrosis

The American Thoracic Society (ATS), European Respiratory Society, Japanese Respiratory Society, and the Latin American Thoracic Association published guidelines in 2011 for the diagnosis and management of individuals with idiopathic fibrosis. Lung transplantation was recommended for appropriately selected individual with idiopathic pulmonary fibrosis (IPF (strong recommendation, low-quality evidence)). An updated to this document was published in 2015 in which the committee did not make a recommendation regarding single versus bilateral lung transplantation for individuals with idiopathic fibrosis. The committee noted that it was unclear which option single or bilateral lung transplantation was preferable for long term outcomes. In 2022, the committee updated guidance on diagnosis and management of IPF and progressive pulmonary fibrosis recommending that individuals at increased risk of mortality should be referred for a lung transplantation upon diagnosis.

Chronic End Stage Lung Disease

The ISHLT 2021 guidelines on the selection of lung transplant candidate states that lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective if there is adequate graft function.

ISHLT 2021 guidelines considers the following as absolute contraindication for a lung transplant.

- Malignancy with high risk of recurrence or death related to cancer.
- Glomerular filtration rate < 40 mL/min/1.73m2 unless being considered for multi-organ transplant.
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia).
- Stroke within 30 days.
- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant.
- Acute liver failure.
- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery.
- Septic shock.
- Active extrapulmonary or disseminated infection.
- HIV infection with detectable viral load.

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- Limited functional status (e.g., non-ambulatory) with poor potential for post-transplant rehabilitation.
- Progressive cognitive impairment.
- Repeated episodes of non-adherence without evidence of improvement (Note: For pediatric individual this is not an absolute contraindication and ongoing assessment of non-adherence should occur as they progress through different developmental stages.)
- Active substance uses or dependence including current tobacco use, vaping, marijuana smoking, or IV drug use.

Cystic Fibrosis

The Cystic Fibrosis Foundation consensus guidelines (2020) for the care of individuals with advanced cystic fibrosis lung disease recommends lung transplantation as a treatment option for individuals with advanced cystic fibrosis lung disease if congruent with goals.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
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
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral

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Code	Description
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral

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HCPCS Codes

Code	Description
No code	

ICD10 Codes

Code	Description
D38.1	Neoplasm of uncertain behavior of trachea, bronchus and lung
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
D86.0-D86.9	Sarcoidosis (code range)
E71.41	Primary carnitine deficiency
E84.0-E84.9	Cystic fibrosis (code range)
126.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.00-I27.9	Other pulmonary heart diseases (code range)
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0-J43.9	Emphysema (code range)
J44.9	Chronic obstructive pulmonary disease, unspecified
J47.9	Bronchiectasis, uncomplicated
J84.10- J84.114	Other interstitial pulmonary diseases with fibrosis (code range)
J84.2	Lymphoid interstitial pneumonia
J84.89	Other specified interstitial pulmonary diseases

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Code	Description
399	Respiratory disorders in diseases classified elsewhere
M32.13	Lung involvement in systemic lupus erythematosus
M33.01- M33.91	Dermatopolymyositis (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)
M35.02	Sicca syndrome with lung involvement
P27.0-P27.9	Chronic respiratory disease originating in the perinatal period (code range)
Q21.0	Ventricular septal defect
Q33.4	Congenital bronchiectasis
T80.0xxA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter
T81.718A	Complication of other artery following a procedure, not elsewhere classified, initial encounter
T81.72xA	Complication of vein following a procedure, not elsewhere classified, initial encounter
T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
T82.818A	Embolism of vascular prosthetic devices, implants and grafts, initial encounter

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SEARCH TERMS

Lobar Lung Transplant, Lung Transplant

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Lung Cancer Screening with Low Dose Computed Tomography (LDCT) (NCD 210.14) [accessed 2025 Apr 22].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

02/21/02, 02/20/03, 01/15/04, 01/20/05, 01/19/06, 02/15/07, 01/17/08, 03/19/09, 03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/19/15, 03/17/16, 03/16/17, 03/15/18, 03/21/19, 03/19/20, 03/18/21, 03/24/22, 05/18/23, 04/18/24, 05/22/25

Date	Summary of Changes
05/22/25	Annual review. Policy intent unchanged.
01/01/25	Summary of changes tracking implemented.
04/20/00	Original effective date