Molina Clinical Policy
Lung Transplantation
Policy No. 115

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Lung transplantation is a surgical procedure performed to replace a diseased lung with a healthy donor lung. Transplant may be required for those with advanced lung disease that do not respond to other treatments or for those with a limited life expectancy (> 50% risk of death) over the next two years if a transplant is not performed ([1-2]Hachem 2024; [1]OPTN 2023). Previously, the number of completed lung transplants were limited due to high mortality rates from intra- and post-surgical complications; however, advances in surgical technique, post-operative management, recipient selection, and advances in immunosuppression have improved lung transplant outcomes. The primary limiting factors for the number of lung transplants performed is a lack of suitable healthy lung donors and potential complications before and after donor brain death that affect the viability of potential donor lungs ([1]Hachem 2024). The number of lung transplants continues to increase, with 3,049 adult and 31 pediatric lung transplants performed in the United States in 2023 (Valapour et al. 2025). The number of candidates added to the transplant waiting list also continues to increase, which led to the development and implementation of the continuous distribution system to improve lung allocation in 2023 ([1-2]OPTN 2023; Valapour et al. 2025). There is also a focus on the management of patients with end-stage lung disease who are waiting for a suitable donor. Management depends on the cause of lung disease and includes, but is not limited to ([2]Hachem 2024):

- Lung volume reduction surgery
- Oxygen therapy
- Pulmonary rehabilitation
- Treatment of reversible airway disease
- Vasodilators
- Pulmonary thromboendarterectomy in patients with chronic pulmonary thromboembolic disease

There are several types of lung transplantation. Single lung transplant, commonly performed in patients with idiopathic pulmonary fibrosis, is utilized to extend the limited supply of donor lungs (Hachem 2025; Hartwig & Klapper 2024). Bilateral lung transplant is mandatory in patients with end stage cystic fibrosis and can be performed sequentially, en bloc, or simultaneously. Bilateral lung transplant is also preferred for patients with severe pulmonary hypertension and bronchiectasis (Hartwig & Klapper 2024). Living donor lobar lung transplantation involves the transplantation of a lung lobe or lobes from one or two healthy donors to replace the diseased lung(s) of a recipient with end-stage lung disease. The indications for this type of transplant include improvement of functional status and quality of life as well as to prolong survival in a patient who requires lung transplantation but whose deteriorating condition will likely lead to death before a cadaveric organ becomes available. Each donor donates only one lung lobe (Hachem 2025). A split lung bilateral lobar transplant, in which, a single left lung from a donor who is approximately 15% taller than the recipient is divided such that the left upper and lower lobes are implanted into the recipient's right and left hemithorax, respectively. The principal advantage of split lung bilateral lobar transplantation is that it permits single lung transplantation from a donor with a large size discrepancy with the recipient, such as a small adult or child (Hachem 2025).

Additionally, retransplantation may occur. Retransplantation refers to replacing a previously transplanted lung or lungs (primary transplant) with a new donor lung or lungs following graft failure. Retransplantation is only considered in carefully selected patients due to the difficulties associated with retransplantation. The surgical procedure is much

more complicated due to the thoracic adhesions present from the primary transplantation. In addition, survival following retransplantation is significantly worse with median survival post-transplant currently 3.1 years versus 6.2 years for primary transplantation (Hachem 2025).

A heart-lung transplant is intended to prolong survival and improve function in recipients with end stage cardiopulmonary disease. Indications for a heart-lung transplant include complex congenital heart disease with Eisenmenger syndrome, nonidiopathic pulmonary hypertension due to congenital heart disease, CF, cardiomyopathy, and idiopathic pulmonary hypertension. In general, a heart-lung transplant is less preferred to isolated lung or heart transplantation as there are disadvantages to combined heart-lung transplantation, such as the need to procure a heart-lung block leading to "increased waiting time and increased mortality" and "exposure of the recipient to the risks of both graft coronary artery vasculopathy and chronic lung allograft dysfunction." In addition, heart-lung transplant recipients may face disadvantages related to the requirement of cardiopulmonary bypass during surgery and the physiological consequences of a denervated heart (Singer & Mooney 2024).

Continuous Distribution Framework and Lung Composite Allocation Score

The Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) began development of the continuous distribution framework in December 2018 to improve the process of matching organ donors with recipients and make organ allocation more equitable and improve waitlist mortality. Under this framework, each candidate is assigned a composite allocation score (CAS) based on attributes such as medical urgency, pediatric age group, post-transplant survival, blood type, sensitization, candidate size, prior living donor status, and placement efficiency. Each attribute has a specific weight that indicates the effect that attribute will have on the total score ([1]OPTN 2023; Valapour et al. 2025). The lung CAS will extend to decimal point values, meaning there should not be many instances where two or more candidates will have the exact same score. If there are two candidates with the same score, the candidate that was registered first will be prioritized to receive the donor lung ([1-3]OPTN 2023).

Conditions Associated with Lung Transplantation

Interstitial lung disease (ILD) is a term used to describe lung diseases that begin in the pulmonary interstitium. The diseases are classified together due to similar clinical, radiographic, physiologic, and/or pathologic manifestations (King 2024). The lung diseases are further grouped according to whether the cause of the disease is known or unknown. Unknown causes of ILD are referred to as idiopathic. Diseases classified as idiopathic ILD include cryptogenic organizing pneumonia, sarcoidosis, and idiopathic interstitial pneumonias (acute, subacute, smoking-related, and chronic fibrosing) (King 2024). Causes of ILD may include infectious organisms (bacterial, fungal, or viral), exposure to occupational or environmental agents, drug-induced pulmonary toxicity, or radiation-induced lung injury (King 2024). Most of the symptoms for each disease process are nonspecific, making it important to determine the duration and severity of symptoms, past medical, family, and social history, results of radiographic imaging of the chest, and pulmonary function test (PFT) results (King 2024). PFT trending can help determine the severity of reduction and is also used as an indicator for lung transplant referral (King 2025; Leard et al. 2021). ILD accounts for approximately 40% of all lung transplants and idiopathic pulmonary fibrosis is the most common form of ILD that is referred for lung transplantation (King 2025; Leard et al. 2021).

Chronic obstructive pulmonary disease (COPD) is the world's fourth leading cause of death according to the World Health Organization (WHO 2024). In the United States, COPD was the fifth leading cause of death in 2023, with an age-adjusted prevalence of 3.8%, increasing with age (Weeks & Elgaddal 2025). However, there may be a significantly higher number of cases yet to be diagnosed as some research shows more than 50% of adults with low pulmonary function were not aware that they had COPD when receiving an official diagnosis (Watson et al. 2024). Women are more likely than men to have COPD, and face higher rates of misdiagnosis or delayed diagnosis than men (Carlson et al. 2022. COPD is typically diagnosed using PFT trending, specifically spirometry. The BODE index is typically used in conjunction with PFTs to assess a patient for referral for transplant evaluation at a transplant center ([2]Hachem 2024). The BODE index provides a score from 0-10 based on **b**ody mass index, airflow **o**bstruction, **d**yspnea, and **e**xercise capacity ([2]Hachem 2024). A higher score indicates a lower 4-year survival rate ([2]Hachem 2024). Approximately 30.6% of all lung transplants occur in individuals with COPD ([1]CDC 2024; GOLD 2023).

Cystic fibrosis (CF) is an inherited genetic disorder resulting from mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. CF is a multisystem disease that causes dysfunction of multiple organs. The most common cause of mortality in patients with CF is pulmonary disease, as CF causes thick, sticky mucus that

blocks the airways and can lead to lung damage. In addition, CF can increase the risk of recurrent respiratory infections due to germs becoming trapped in the mucus. Those with CF have a decreased ability to absorb nutrients from food due to pancreatic duct obstruction and proteins needed for digestion not reaching the intestines. Various organs can be affected by CF which may lead to other health conditions such as diabetes, cirrhosis of the liver, arthritis, reflux, hypersplenism, and osteoporosis. Due to being inherited, genetic counseling and testing is recommended if there is a family history of CF. Screening for CF is part of newborn screening panels in the United States as early detection allows for early treatment. Regular treatments for CF consist of CFTR modulators, airway clearance therapies, bronchodilators, pancreatic enzyme replacement therapies, anti-inflammatory therapies, and infection prevention. Routine PFTs are also performed to assess and trend lung function. Lung transplantation may be indicated if the disease progresses and symptoms such as massive hemoptysis and recurrent pneumothorax develop. Other indications for referral for transplant evaluation include rapidly declining PFT results, ≥ 2 exacerbations per year requiring intravenous antibiotics, a body mass index < 18 despite improving nutritional status, and hypoxemia or hypercarbia (Ramos et al. 2019; Simon 2025). Referral for a transplant evaluation is recommended earlier in the disease process "to allow patients and their families to better prepare for transplantation medically and psychologically" ([2]Hachem 2024). Approximately 35,000 people in the United States have cystic fibrosis ([2]CDC 2024).

Bronchopulmonary dysplasia (BPD) is a chronic lung disease that is most common in low-birthweight or premature infants who require prolonged supplemental oxygen or mechanical ventilation due to underdeveloped and immature lungs, but may also affect older infants born with conditions that affect normal lung development, or that had infection before birth or placental abnormalities. BPD is not a condition infants are born with but instead results from damage to the lungs. While most children recover, BPD may cause long-term breathing difficulties due to progressive pulmonary deterioration which could warrant a lung transplant in select cases. The disease affects 10,000-15,000 infants annually in the United States. The risk of developing BPD increases with a lower birth weight (< 2.2 pounds) and a lower gestational age at birth. As the survival of low-birth weight infants has steadily improved, the incidence of BPD has also increased, as medical teams are able to keep infants with much lower gestational ages and birth weights alive compared to the past due to advances in medicine, such as surfactant and improved mechanical ventilation and non-invasive ventilation strategies. These newer cases of BPD may be less associated with lung injury from supplemental oxygen and ventilation and more associated with disruptions in lung development (Dani et al. 2023; NORD 2023; Stark & Eichenwald 2025).

Other conditions that may warrant lung transplantation include idiopathic pulmonary atrial hypertension, and certain cases of congenital heart disease or defects (typically requiring heart-lung transplant rather than lung alone). Hereditary conditions and other rare diseases causing severe lung damage, such as sarcoidosis, pulmonary Langerhans cell histiocytosis, and lymphangioleiomyomatosis (LAM) may also necessitate transplantation. *Lung cancer is not a condition for which transplant is generally recommended due to the risk of cancer recurrence* ([2]Hachem 2024; Singer & Mooney 2024).

RELATED POLICIES

MCP-459 Pre-Transplant and Transplant Evaluation
MCP-116: Heart Transplant

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant

Adult and Pediatric Criteria for Lung Transplantation

Lung transplantation may be **considered medically necessary** when the Member meets ALL the following criteria:

1) All transplant evaluation criteria are met as stipulated in MCP 459

2) Documentation that all applicable medical, pharmaceutical, and surgical alternatives to lung transplant have been utilized (e.g., oxygen therapy, pulmonary rehabilitation, lung volume reduction surgery for patients with COPD)

3) For multi-organ heart and lung transplant requests: Criteria must be met for each organ requested (see individual policy for heart transplantation criteria)

4) For Living Donor lobar lung transplant requests: Additional documentation supporting the Member's inability to survive the wait for a deceased donor allograft is required and includes ALL the following:
   a. Affirmation that if donor lobar lung transplant is not performed, Member may become ineligible for lung transplantation due to clinical deterioration
   b. Member is ambulatory and meets requirements to receive pulmonary rehab
   c. Evidence of end stage pulmonary disease with a life expectancy < 18 months without a transplant
   d. Absence of other serious systemic disease or condition affecting long term survival
   e. Documented history of medical treatment compliance

5) Member meets disease-specific criteria for ONE of the following conditions:
   a. **Chronic Obstructive Pulmonary Disease (COPD)** (e.g., COPD, emphysema, alpha-1 antitrypsin disease, Bronchiolitis Obliterans Syndrome, bronchiectasis): Single or bilateral lung transplantation is indicated when ALL the following criteria are met:
      i. BODE index score of ≥ 7
      ii. The presence of at least ONE of the following conditions:
         1) History of hospitalization for severe COPD exacerbation with acute hypercapnia (partial pressure of carbon dioxide in arterial blood [$PaCO_2$] ≥ 50 mmHg)
         2) ≥ 3 severe exacerbations within the preceding year
         3) Refractory dependence on noninvasive ventilatory assistance
         4) Forced Expiratory Volume in 1 Second (FEV_1) < 20% predicted, without reversibility
         5) Chronic hypercapnia ($PaCO_2$ ≥ 50 mmHg) with progressive deterioration requiring long term oxygen therapy (defined as ≥ 6 months)
         6) Moderate to severe pulmonary hypertension (e.g., mean pulmonary artery pressure [mPAP] > 35 mmHg or mean right atrial pressure > 15 mmHg) or cor pulmonale despite oxygen therapy
   b. **Cystic Fibrosis:** Bilateral lung transplantation is indicated when ALL the following criteria are met:
      i. Members with a FEV_1 < 30% *or* rapid decline in lung function (≥ 30% relative decline in FEV_1 over 12 months)
      ii. The presence of at least ONE of the following conditions:
         1) Chronic respiratory failure with hypoxemia or hypercapnia ($PaCO_2$ ≥ 50 mmHg), particularly for those with increasing oxygen requirements or needing long-term non-invasive ventilation therapy
         2) Pulmonary hypertension (pulmonary artery [PA] systolic pressure > 50 mmHg on echocardiogram or evidence of right ventricular dysfunction)
         3) Refractory and/or recurrent pneumothorax
         4) An exacerbation requiring mechanical invasive ventilation or frequent hospitalization (> 28 days hospitalized), in the last year
         5) Worsening nutritional status, particularly with BMI < 18 kg/m^2, despite nutritional interventions
         6) Recurrent life-threatening hemoptysis despite bronchial artery embolization

c. **Interstitial Lung Disease (ILD)** (e.g., idiopathic pulmonary fibrosis, interstitial pneumonia, sarcoidosis): Single or bilateral lung transplantation is indicated when the following criteria are met:
   i. Symptomatic, progressive disease unresponsive to optimal therapy (e.g., pharmacologic therapy, supplemental oxygen, pulmonary rehabilitation)
   ii. Histologic or radiographic evidence of interstitial lung disease
   iii. The presence of at least ONE of the following:
      1) Absolute decline in forced vital capacity (FVC) > 10% or > 5% with radiologic progression, in the past 6 months
      2) Absolute decline in diffusion capacity for carbon monoxide (DLCO) > 10% in the past 6 months
      3) Extensive reticulation or honeycomb change on CT scan
      4) Oxygen desaturation to < 88% during 6-minute walk test (6MWT) or decrease in 6MWT by > 50m over 6 months
      5) Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography (in the absence of diastolic dysfunction)
      6) Hospitalization due to respiratory decline, pneumothorax, or acute exacerbation
   iv. For Members with **systemic scleroderma (SSc)**: In addition to the above criteria, documentation of a comprehensive multi-organ evaluation of gastrointestinal (i.e., esophageal dysfunction, GI dysmotility, gastroesophageal reflux), renal, and cardiac involvement and clearance is required

d. **Lymphangioleiomyomatosis (LAM):** Single or bilateral lung transplantation is indicated when ALL the following criteria are met:
   i. Evidence of disease progression despite mTOR inhibitor therapy
   ii. The presence of at least ONE of the following conditions:
      1) Severe lung function impairment (FEV_1 < 30% predicted)
      2) Exertional dyspnea (NYHA class III or IV)
      3) Hypoxemia at rest
      4) Pulmonary hypertension
      5) Refractory pneumothorax

e. **Pulmonary Sarcoidosis:** Single or bilateral lung transplantation is indicated in Members with disease progression despite optimal therapy when ALL the following criteria are met:
   i. Stage IV radiographic disease (i.e., advanced fibrotic changes, honeycombing, hilar retraction, and cystic change)
   ii. New York Heart Association (NYHA) functional class III or IV and ANY of the following:
      1) Severe pulmonary hypertension
      2) Oxygen dependence

f. **Pulmonary Hypertension** (e.g., idiopathic pulmonary arterial hypertension, chronic thromboembolic pulmonary hypertension [CTEPH], Eisenmenger syndrome): Bilateral lung transplantation is indicated when ALL the following criteria are met:
   i. Unsuccessful control of pulmonary hypertension with appropriate pharmacologic agents (e.g., calcium channel blockers, endothelin receptor antagonists, prostacyclin analogues, etc.)
   ii. ANY of the following:
      1) *For adult patients:* European Society of Cardiology/European Respiratory Society (ESC/ERS) high risk category *or* REVEAL risk score >10
      2) *For pediatric patients:* European Pediatric Pulmonary Vascular Disease Network (EPPVDN) high risk category
      3) Progressive hypoxemia
      4) Progressive, but not end-stage, liver or kidney dysfunction due to pulmonary arterial hypertension
      5) Life-threatening hemoptysis
      6) Persistent NYHA functional class III or IV despite maximal medical therapy for 3 months (e.g., combination therapy including prostanoids)
      7) Six-minute walk test of < 350m
      8) Cardiac index < 2 liters per minute per square meter
      9) Right atrial pressure >15 mmHg
      10) Mean pulmonary arterial pressure > 20 mmHg

11) Refractory right heart failure (progressive renal insufficiency, increasing bilirubin, refractory ascites, increasing brain natriuretic peptide levels)

iii. For Members with **advanced refractory CTEPH**: No feasible pulmonary thromboendarterectomy

iv. For Members with **systemic scleroderma (SSc)**: In addition to the above criteria, documentation of a comprehensive multi-organ evaluation of gastrointestinal (i.e., esophageal dysfunction, GI dysmotility, gastroesophageal reflux), renal, and cardiac involvement and clearance is required

g. **Pulmonary Langerhans Cell Histiocytosis / Eosinophilic Granuloma:** Single or bilateral lung transplantation is indicated when ANY of the following criteria are met:
   i. Severe lung function impairment (FEV_1 < 30% predicted)
   ii. Severe impairment in exercise capacity (VO_2 max < 50% predicted)
   iii. Hypoxemia at rest (PaO_2 < 55 mmHg)

h. **Graft versus host disease**: Single or bilateral lung transplantation is indicated when ANY of the following criteria are met:
   i. Progressive lung damage resulting in severe compromise of activities of daily living
   ii. Life expectancy limited by lung disease

i. Bilateral lung transplantation is indicated when Member has any **other end-stage lung disease not expected to recover without transplant** (e.g., pulmonary hypoplasia, bronchopulmonary dysplasia, surfactant disorders, hereditary hemorrhagic telangiectasia, prolonged acute respiratory distress syndrome [ARDS], or acute fulminant lung damage including post-coronavirus 2019 [COVID-19] infection)

Adult and Pediatric Criteria for Heart-Lung Transplantation

A simultaneous heart and lung transplantation may be **considered medically necessary** when ALL the following criteria are met:

1. Severe refractory end-stage heart failure

2. ONE of the following pulmonary conditions:
   a. End-stage lung disease
   b. Irreversible pulmonary hypertension

3. ONE of the following underlying conditions:
   a. Congenital heart disease with Eisenmenger syndrome
   b. Cystic fibrosis
   c. End-stage parenchymal lung disease with severely compromised left ventricular function (e.g., sarcoidosis)

Adult and Pediatric Criteria for Retransplantation

Retransplantation may be **considered medically necessary** when ALL the following criteria are met:

1. Member is ventilator independent

2. Member is free of significant co-morbidities

3. Member meets all other requirements for transplantation outlined above AND has *one* of these indications:
   a. Non-function of the grafted organ
   b. Rejection refractory to immunosuppressive therapy
   c. Bronchiolitis obliterans (chronic rejection)
   d. Airway complications not correctable by other measures

Limitations and Exclusions

Requests for third or subsequent lung transplantation are considered **not medically necessary** and may not be authorized

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

National and Specialty Organizations

The **Global Initiative for Chronic Obstructive Lung Disease (GOLD)** published *Global strategy for prevention, diagnosis and management of COPD: 2024 report* for the diagnosis, management, and prevention of COPD. Recommendations specific to lung transplant referral include patients with COPD who "have progressive disease despite maximal medical treatment, are not candidates for lung volume reduction surgery, have a BODE index of 5 to 6, a $PaCO_2$ > 50 mg and/or PaO_2 < 60 mmHg and FEV_1 < 25%." GOLD recommends that patients be listed for transplant "when the BODE index is > 7, FEV_1 is < 15-20%, and they have had three or more severe exacerbations during the previous year, one severe exacerbation with hypercapnic respiratory failure, or have moderate to severe pulmonary hypertension." GOLD notes that over 70% of lung transplants in patients with COPD are bilateral lung transplants. Single lung transplants may be performed in patients with COPD but there are potential complications for the native lung, including hyperinflation (15-30% occurrence rate) and lung cancer (occurrence rate 5.2-6.1%). Additionally, patients with advanced emphysema may require lung volume reduction surgery or endoscopic lung volume reduction in the native lung to treat hyperinflation following single lung transplantation. Patients with advanced emphysema may also undergo lung volume reduction surgery or endoscopic lung volume reduction prior to lung transplantation to delay the need for transplant or optimize their condition prior to lung transplantation. Lung volume reduction surgery may be performed in one or both lungs (GOLD 2024).

The **European Society of Cardiology and European Respiratory Society (ESC/ERS)** published the *2022 ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension*. The guidelines recommend evaluation for lung transplant referral in patients that are refractory to optimized medical therapy, present with an intermediate-high or high-risk of death and have a disease variant that responds poorly to medical therapy. The guidelines also recommend referral for progressive disease or recent hospitalization for worsening pulmonary hypertension, a need for intravenous or subcutaneous prostacyclin therapy, and signs of secondary liver or kidney dysfunction due to pulmonary hypertension or other potentially life-threatening complications. Heart-lung transplantation remains an option for those with significant cardiac and pulmonary dysfunction; however, heart-lung transplantation remains limited by the availability of organs and the complexities of a combined heart-lung transplantation. The ESC/ERS states that connective tissue disease is not a contraindication for lung transplantation (Humbert et al. 2022).

The ESC/ERS recommends listing patients for lung transplant who present with a high risk of death or with a Registry to Evaluate Early and Long-term Pulmonary Arterial Hypertension Disease Management (REVEAL) score ≥ 10 despite receiving optimized medical therapy, including subcutaneous or intravenous prostacyclin analogues. Most patients with pulmonary arterial hypertension receive bilaterial lung transplant, while combined heart-lung transplant is typically reserved for select patients who have additional cardiac conditions that cannot be corrected (Humbert et al. 2022).

The ESC/ERS guidelines note that Eisenmenger syndrome is an advanced form of adult congenital heart disease associated with pulmonary arterial hypertension. The disease is characterized by chronic hypoxemia, cyanosis, hematological changes (e.g., secondary erythrocytosis and thrombocytopenia), and may present with hemoptysis, chest pain, cerebrovascular accidents, brain abscess, coagulation abnormalities, and sudden death. Lung transplantation or heart-lung transplantation with heart surgery is an option in highly select cases when a patient is not responsive to medical treatment. Mortality is high during the first year after surgery, especially after heart-lung transplantation (Humbert et al. 2022).

The ESC/ERS guidelines recommend surgical pulmonary endarterectomy (or pulmonary thromboendarterectomy) as the treatment of choice for patients with chronic thromboembolic pulmonary hypertension (CTEPH) and fibrotic obstructions within pulmonary arteries that are accessible by surgery (Class I recommendation, Level B evidence). For patients who are inoperable or who have residual pulmonary hypertension after pulmonary thromboendarterectomy,

balloon pulmonary angioplasty and/or targeted medical therapy (e.g., ricociguat) are recommended (Class I recommendation, Level B evidence) (Humbert et al. 2022).

The **American Lung Association** also recognizes that the primary treatment method for CTEPH is pulmonary thromboendarterectomy. However, more than one-third of CTEPH patients are not good candidates for this surgery, such as those with distal lesions that are difficult to reach with surgery or those with other medical conditions. While balloon pulmonary angioplasty and/or medication are treatment alternatives, the American Lung Association also notes that lung transplant may be recommended for patients with advanced CTEPH when other treatment options fail (American Lung Association 2024).

The **International Society for Heart and Lung Transplantation (ISHLT)** published the *Consensus Document for the Selection of Lung Transplant Candidates* which provides guidance regarding timely referral, assessment, optimization, and listing of potential lung transplant candidates. The 2021 report highlights how comorbidities and other risk factors interact to affect post-transplant survival benefit. The guidelines also list absolute contraindications and notes that "most lung transplant programs should not transplant patients with [those] risk factors except under very exceptional or extenuating circumstances." The ISHLT agrees that lung transplantation improves survival and quality of life. However, the panel acknowledges that when making recommendations about allocating a scarce resource, survival benefit should be prioritized. The ISHLT consensus document provides important disease specific considerations to guide referral and listing of potential lung transplant candidates. Recommendations reflect expert synthesis of current literature (Leard et al. 2021). The ISHLT provides the following disease-specific considerations for listing:

COPD: The ISHLT recommends timing of listing when the BODE index reaches 7-10. Additional factors that may prompt listing include a FEV_1 < 20% predicted, the presence of moderate to severe pulmonary hypertension, a history of severe COPD exacerbations, and chronic hypercapnia. The ISHLT notes that the BODE index has been cited as the prognostic model of choice by the GOLD and stands as the best guideline for listing patients. However, research has shown that the BODE index may overestimate mortality in lung transplant candidates with COPD, including patients with alpha-1-antityrpsin deficiency. Therefore, an FEV_1 < 20% predicted and other factors associated with increased mortality may be considered for listing (Leard et al. 2021).

Cystic Fibrosis: The ISHLT recommends timing of listing when referral criteria are met (e.g., trial of cystic fibrosis transmembrane conductance regulator [CFTR] modulators and indications of advanced lung disease) in combination with markers of severe and progressive disease, such as FEV_1 < 25% predicted, rapid decline in lung function (> 30% relative decline in FEV_1 over 12 months), frequent hospitalization, any exacerbation requiring mechanical ventilation, chronic respiratory failure with hypoxemia or hypercapnia, pulmonary hypertension (PA systolic pressure > 50 mmHG or evidence of right ventricular dysfunction, worsening nutritional status, recurrent massive hemoptysis despite bronchial artery embolization, and World Health Organization function class IV. The ISHLT also notes that in patients with CF, "a lower threshold for both referral and listing should be considered in females, patients with short stature, diabetes, or increasing antibiotic resistance, including infection with *Burkholderia cepacian* complex or nontuberculous mycobacteria. All transplant candidates with CF should be evaluated for *Burkholderia cepacian* complex, nontuberculous mycobacteria, and fungal pathogens" (Leard et al. 2021).

Interstitial Lung Disease: The ISHLT recommends timing of listing when any form of pulmonary fibrosis is present with an absolute decline in FVC (> 10% or > 5% with radiologic progression) or absolute decline in DLCO (> 10%) in the past 6 months despite appropriate treatment. Additionally, the ISHLT recommends listing when any of the following are present: desaturation < 88% on 6MWT or > 50m decline in 6MWT in the past 6 months, pulmonary hypertension on right catheterization or 2D echocardiogram in the absence of diastolic dysfunction, or hospitalization because of respiratory decline, pneumothorax, or acute exacerbation. The ISHLT also notes that patients with sarcoidosis may need additional evaluation to examine the extent of possible cardiac involvement and to exclude malignancy as an etiology for lymphadenopathy. In patients with concomitant emphysema, FVC may be a less reliable marker (Leard et al. 2021).

Pulmonary Hypertension: The ISHLT recommends timing of listing for pulmonary atrial hypertension when ESC/ERS risk stratification is graded as high risk or with a REVEAL risk score > 10, despite being treated with appropriate pulmonary atrial hypertension therapy (including prostacyclin analogues). Alternative criteria for listing include progressive hypoxemia (especially in patients with pulmonary veno-occlusive disease or pulmonary capillary hemangiomatosis), life-threatening hemoptysis, and progressive (but not end-stage) liver or kidney dysfunction due to pulmonary atrial hypertension (Leard et al. 2021).

The ISHLT also notes that approximately 5% of lung transplants are re-transplants; however, outcomes for re-transplants are inferior, particularly if the re-transplant is done within the first year after the original or if the patient has restrictive allograft syndrome. Therefore, the pre-transplant evaluation for re-transplant candidates should focus on understanding the possible reasons for graft failure, such as alloimmunization, poor compliance, gastroesophageal reflux, or repeat infections. Multi-organ transplant, such as heart-lung transplant, might be considered in cases where survival with isolated transplant is unlikely without simultaneous transplant of another organ. It may also be considered in cases where significant post-transplant organ dysfunction is anticipated if isolated lung transplant is performed. Approximately 1.6% of lung transplants are multi-organ transplants and face a higher waiting list mortality than single organ transplant candidates. The primary indication for heart-lung transplant is pulmonary hypertension secondary to either congenital heart disease or idiopathic pulmonary arterial hypertension (Leard et al. 2021).

The **ISHLT** published a *consensus document on lung transplant in patients with connective tissue disease.* The guidelines state that lung transplantation should be considered in patients with connective tissue disorders with advanced lung disease whose clinical status has progressively declined despite optimal medical management. For patients with systemic sclerosis (or scleroderma), disease may be classified under a specific phenotype. For example, patients may have predominately interstitial lung disease, predominately pulmonary arterial hypertension, or a combination of interstitial lung disease and pulmonary hypertension. These pulmonary phenotypes can guide risk stratification for lung transplant candidates with systemic sclerosis. The authors note that patients with connective tissue disease are complex, and involvement of a multidisciplinary team evaluation is strongly advised. For patients with systemic sclerosis, the ISHLT recommends evaluation of the following extrapulmonary systems: cardiac, vascular (e.g., Raynaud's phenomenon, venous thromboembolism), renal (e.g., scleroderma renal crisis), and gastrointestinal. The authors also note that outcomes for patients undergoing lung transplant for systemic sclerosis are comparable to those undergoing transplant for interstitial lung disease. However, severe pulmonary arterial hypertension and high BMI are high-risk factors for poor survival post-transplant (Crespo et al. 2021).

The **Cystic Fibrosis Foundation** published consensus guidelines for lung transplant referral for individuals with CF (Ramos et al. 2019). The following are indications for lung transplant referral:

- Patients that have an FEV_1 < 50% of predicted
- Patients that have an FEV_1 < 40% predicted and > 2 exacerbations per year requiring intravenous antibiotics or 1 exacerbation requiring positive pressure ventilation regardless of FEV_1
- Those ≥ 18 years of age who have an FEV_1 < 50% of predicted and rapidly declining (>20% relative decline within 12 months) or FEV_1 < 40% of predicted with markers of shortened survival or FEV_1 < 30% of predicted
- Those < 18 years of age who have an FEV_1 < 50% of predicted and rapidly declining (>20 relative decline within 12 months) or FEV_1 is < 50% of predicted with markers of shortened survival or FEV_1 < 40% of predicted
- Adults with a body mass index < 18 and FEV1 < 40% predicted while concurrently working to improve nutritional state
- Patients with an FEV_1 < 40% predicted and massive hemoptysis requiring intensive care admission or bronchial artery embolization
- Patients with an FEV_1 < 40% and a pneumothorax

Markers of shortened survival include a 6-minute walk test distance < 400 meters, hypoxemia at rest or with exertion, hypercarbia ($PaCO_2$ > 50 mmHg) on arterial blood gas, and pulmonary hypertension on echocardiogram (PA systolic pressure > 50 mmHg) or evidence of right ventricular dysfunction in the absence of a tricuspid regurgitant jet. The Cystic Fibrosis Foundation also recommends ensuring modifiable barriers, such as nutritional status, diabetes management, physical inactivity or deconditioning, adherence behaviors, mental health issues, substance use, and psychosocial factors be addressed preemptively to optimize transplant candidacy.

National Institute for Health and Clinical Excellence (NICE): The 2018 guidance *Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management (NG115)* provides guidance for COPD as well as emphysema and chronic bronchitis in individuals aged 16 and older. A goal is to help providers diagnose patients earlier to obtain optimal benefit from treatments and improve quality of life.

Two major recommendations are also included (NICE 2018). First, referrals should be considered to a multidisciplinary team including lung transplantation specialists for patients who:

- Have severe COPD with FEV_1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment

- Are non-smokers
- Have completed pulmonary rehabilitation
- Do not have contraindications for transplantation such as comorbidities or frailty

Secondly, NICE recommends that providers do not use previous lung volume reduction procedures as a reason not to refer a person for assessment for lung transplantation. This was modified previously as evidence demonstrated that those with severe COPD had improvements in lung function, exercise capacity, quality of life, and long-term mortality as a result of lung volume reduction surgery.

NICE also published guidelines in 2017 for the diagnosis and management of interstitial pulmonary fibrosis (NICE 2017). Recommendations specific to lung transplantation include discussing transplantation as a treatment option between 3-6 months after diagnosis unless clinical condition warrants earlier referral and provided there are no absolute contraindications to transplant.

SUPPLEMENTAL INFORMATION

Pulmonary Function Tests

PFTs are performed to assess pulmonary function in patients that have a history, risk factors, or symptoms of lung disease. There are numerous forms of PFTs that may be performed in outpatient or inpatient settings. The outpatient setting is generally preferred as a greater range of testing may be performed with better accuracy. Results from PFTs are interpreted to determine the degree and type of physiologic impairment (restrictive or obstructive). The most common types of PFTs are spirometry, pre- and post-bronchodilator spirometry, lung volumes, and diffusing capacity for carbon monoxide. The most common measurements are (Kaminsky 2023):

- **FVC**: total exhaled volume after maximum inspiration
- **FEV_1**: the total volume exhaled in the first second of forceful and complete exhalation
- **FEV_1/FVC**: the proportion of a person's vital capacity they can expire in the first second of forced expiration to the full FVC
- **DLCO**: measurement of the diffusing capacity of carbon monoxide in a single breath

New York Heart Association (NYHA) Functional Classification

NYHA classification has served as a vital tool for risk stratification of heart failure and for determining clinical trial eligibility and medication and device candidate eligibility (AHA 2023):

- **Class I**: Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- **Class II**: Individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III**: Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- **Class IV**: Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of HF or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

BODE Index

The BODE index is a measurement to assess risk of mortality in patients with COPD and uses the following factors as indicators: weight (BMI), airway obstruction (FEV1), dyspnea, and exercise capacity. Factors are calculated together, and the approximate four-year survival interpretation is: 0-2 = 80%, 3-4 = 67%, 5-6 = 57%, 7-10 = 18% ([2]Hachem 2024).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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
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
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
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor
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 pre- and post-transplant care in the global definition

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/08/2025	Policy revised. Updated the following disease specific criteria to align with updated guidelines: cystic fibrosis, interstitial lung disease (ILD), LAM, pulmonary Langerhans, sarcoidosis, scleroderma, pulmonary hypertension (PH), and Eisenmenger syndrome. Reorganized scleroderma to fall under ILD and PH, and reorganized Eisenmenger to fall under PH. Separated LAM from pulmonary Langerhans into its own section. Removed ambulatory requirement for adult and pediatric retransplantation. IRO peer reviewed on September 16, 2025 by a practicing physician board certified in pulmonary disease, internal medicine, and critical care.
10/09/2024	Policy reviewed. No changes to coverage criteria.
06/12/2024	Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and Transplant Evaluation.
10/12/2023	Policy reviewed, changes to criteria include addition of other end-stage lung disease criteria, removed rapid fall in FEV1 for CF, age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria, removal of abnormal serology criteria and cannabis use section, and added substance use/vaping/smoking/inhaled cannabis to absolute contraindications. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on September 22, 2023, by a practicing, board-certified physician with specialties in Surgery, Vascular Surgery, and Surgical Critical Care.
10/12/2022	Policy reviewed, no changes to criteria, included section on marijuana use, updated Overview and Summary of Medical Evidence.
10/13/2021	Policy reviewed, no criteria updates, updated references. Coding section updated; removed CPT codes 33930, 33933, 33935.
09/16/2020	Policy updated with additional disease specific criteria for COPD, cystic fibrosis, congenital heart disease, interstitial lung disease,

	PAH, PLCH, and graft vs. host disease, updated references.
09/18/2019	Policy reviewed, no changes.
09/13/2018	Policy reviewed, no changes.
06/22/2017	Policy reviewed, no changes.
09/15/2016	Policy reviewed, no changes.
04/27/2015	Policy updated with new pretransplant criteria; Summary of Medical Evidence section condensed. Added one new indication for individuals with scleroderma.
08/30/2012	New policy.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

This policy contains prior authorization requirements.