

Molina Clinical Policy

Lung Transplantation: Policy No. 115

Last Approval: 10/12/2022

Next Review Due By: October 2023



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 performed to replace a diseased lung to with a healthy donor lung. Surgery can typically be performed on people of all ages. Types of transplants include single, double, bilateral sequential, or heart-lung transplant. Transplant may be required for those with lung issues that do not respond to other treatment as well as those with a life expectancy of 12 to 24 months without a transplant. (Johns Hopkins, n.d.). The conditions described below may warrant lung transplantation:

Chronic Obstructive Pulmonary Disease (COPD) is the world's third leading cause of death according to the World Health Organizations (WHO, 2020). In the United States, COPD was the fourth leading cause of death – approximately 15.7 million Americans (6.4%) have been diagnosed with the disease. The number of cases may be higher as over 50% of adults with low pulmonary function were not aware that they had COPD when diagnosed. Previously, men had higher rates of death from COPD than women however, cases have steadily increased. Women are typically diagnosed later than men once the disease is more advanced, making treatment less effective. In addition, women appear to be more vulnerable to the effects of tobacco and air pollution. For example, the cause of COPD in men is likely to be from tobacco smoke whereas women report lower smoking habits. Those with a history of asthma are also at risk of developing COPD. People with COPD also are (CDC, 2021):

- Over age 65
- American Indians/Alaska Natives and multiracial non-Hispanics
- Unemployed, retired, or unable to work
- Divorced, widowed, or separated
- Current or former smokers

Severe Cystic Fibrosis (CF) is inherited and causes issues in glands that make sweat and mucus; the disease progresses and is usually fatal. The disease results in thick, sticky mucus that blocks airways and can lead to lung damage. In addition, CF can increase the risk of infection due to germs becoming trapped. Various organs can be affected by CF which may lead to other health conditions (e.g., diabetes, cirrhosis of the liver, arthritis, reflux, hypersplenism, and osteoporosis). Approximately 35,000 people in the United States have cystic fibrosis (CDC, 2022).

Bronchopulmonary dysplasia (BPD) is a chronic lung disease that affects newborns may interfere with normal breathing. Oxygen therapy for infants born prematurely with BPD. While many children recover, BPD may cause long-term breathing difficulties which could warrant a lung transplant (ALA, n.d.). The disease affects 10,000-15,000 infants annually in the United States. Risk increases the earlier a baby is born and the lower its birth weight; infants weighing less than 2.2 pounds at birth are at the greatest risk. Due to advances in medicine, the number of cases has increased – doctors are able to keep more low birth weight, premature infants alive longer than in the past. (NORD, 2018).

Other conditions that may warrant lung transplantation include pulmonary hypertension, heart disease or heart defects, and pulmonary fibrosis. Hereditary conditions and other diseases causing severe lung damage such as sarcoidosis, histiocytosis, and lymphangiomyomatosis may also necessitate transplantation. *Lung cancer is not a condition for which transplant is recommended.*

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Transplant Risks

Risks of lung transplantation include bleeding; infection; blockage of the blood vessels to the new lung(s); blockage of the airways; severe pulmonary edema (fluid in the lung); and blood clots. A major risk of transplant is rejection, the body's normal reaction to a foreign object or tissue. Medications are typically used to help the immune system to not attacking the transplant; these medications have side effects. Contraindications for lung transplant include patients with any of the following: (Johns Hopkins, n.d.)

- Untreatable current or recurring infection
- Metastatic cancer
- Severe heart problems
- Unable to tolerate surgery due to other health issues
- Serious health conditions (other than lung disease) that will not improve following transplant
- Unable to be compliant with treatment, pre- and post-transplant

Types of Lung Transplantation

Lung transplantation is a viable treatment option for selected patients with end-stage lung disease due to a wide variety of underlying disorders. Living donor lobar lung transplantation has shown success and addresses the shortage of cadaveric organs. (Hartwig & Klapper, 2021).

- **Single lung transplantation** is most effective for patients with end-stage pulmonary fibrosis
- **Double lung transplantation** is most effective in patients with end-stage chronic obstructive pulmonary disease (COPD) and cystic fibrosis
- **Lobar lung transplantation** is usually reserved for pediatric patients who are not expected to survive the waiting time for cadaveric transplant.

The most common indications for pediatric lung transplantation are cystic fibrosis with end stage lung disease, pulmonary hypertension, and pulmonary fibrosis. The goal of lung transplantation is to improve quality of life and long-term survival in patients with end-stage pulmonary disease. Advances in donor and recipient selection, new immunosuppressive medications, new and improved surgical techniques, and increased medical management of infections have improved the overall survival in patients after lung transplantation. (Hartwig & Klapper, 2021).

Single Lung Transplantation. This type of transplant is commonly performed in patients with idiopathic pulmonary fibrosis. A single lung transplant requires 4 to 8 hours and begins when the donor lung arrives in the operating room. A history of prior chest surgery may complicate the procedure and require additional time. The lung with worse pulmonary function is chosen for replacement. If both lungs function equally, then the right lung is usually favored for removal, as this avoids having to maneuver around the heart which is required for excision of the left lung. Single lung transplants are usually done through an incision extending from under the shoulder blade around the chest, ending near the sternum. An alternative method is an incision under the breastbone. Following excision of the native lung, the donor lung is wrapped in sponges soaked with a cold crystalloid solution and placed into the hemithorax. The bronchial anastomosis is performed first. The length of both the donor and recipient bronchi is minimized to preserve collateral blood supply and to achieve some degree of anastomotic overlap. After completion of the anastomoses, the lung is reinflated, and a bronchoscopy is performed to clear remaining blood and mucus from the new lung. Once the performance of the lung is confirmed, the chest incision is closed. (Hachem, 2022).

Double Lung Transplantation. A double (bilateral) lung transplant can be performed sequentially, en bloc, or simultaneously. The most frequently performed procedure is a bilateral sequential single lung transplantation and requires 6 to 12 hours. A clamshell incision is made across the entire chest, just below the breasts. Mobilization and pneumonectomy of the native lung and the implantation of the lung graft are conducted in the same manner as described for single lung transplantation. Removal of both lungs is mandatory in patients with end stage cystic fibrosis therefore double lung transplants is preferred. Double lung transplant is also preferred for patients with pulmonary artery hypertension. (Hachem, 2022).

Heart-Lung Transplantation. A procedure that includes transplantation of one or both lungs and heart from a single cadaver donor. A combined heart-lung transplant is intended to prolong survival and improve function in recipients with end stage cardiopulmonary disease. The surgical technique requires a coordinated triple operative procedure that

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includes the procurement of a donor heart-lung block, surgical removal of the heart and lungs of a single cadaver donor, and implantation of the heart and lungs into the recipient. (Singer & Mooney, 2022).

Living Donor Lobar Transplantation. 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. Objectives of surgery 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. The decision concerning which lobe should be donated is based on an optimal size match between the potential donor and the recipient. While the donor lobectomies are taking place, the recipient undergoes pneumonectomy in another operating suite. Surgery is usually performed through a unilateral or bilateral transverse thoracosternotomy incision, for implantation of one or two lobes, respectively. Most living donor lung recipients are patients with cystic fibrosis and most lung donors are first-degree relatives who are compatible in terms of size and ABO blood group. Living donation is an alternative to cadaveric organ donation particularly when cadaveric transplantation is unavailable, or in patients who are deteriorating clinically to the point of transplant ineligibility while waiting for a cadaveric donor. Living donation may also be an option for critically ill children, due to a shortage of suitable cadaveric donors for this age. (Hayes, 2008).

Split Lung Bilateral Lobar Transplantation. With this procedure, 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. Post operatively, transplant rejection is a primary concern, both immediately after surgery and continuing throughout the patient's life. Signs of rejection are fever, flu-like symptoms, increased difficulty breathing, worsening pulmonary test results, increased chest pain or tenderness, or an increase or decrease in body weight >2 kilograms (kg) per 24 hours. To prevent transplant rejection and subsequent damage to the new lung or lungs, patients must commit to a lifelong regimen of immunosuppressive drugs. Treatment of chronic rejection is the most difficult issue following lung transplantation. Transplant patients are vulnerable to infections. Antibiotics may be prescribed to treat or prevent infections. Certain medications may also have side effects or trigger allergic reactions. Close follow-up care is required to balance the benefits and potential risks of the drugs. The early postoperative period is the first 3 months following transplantation. Chest x-rays are performed according to the patient's clinical status. Spirometry is done after surgery, at pre-discharge, and periodically thereafter. Fiberoptic bronchoscopy and bronchoalveolar lavage are performed if the patient demonstrates new infiltrates on chest radiographs, a decrease in lung function on spirometry, or the presence of new symptoms. Depending on the center, routine transbronchial lung biopsy in asymptomatic patients with stable lung function is performed. Late monitoring begins after the third month following transplantation and includes mainly monitoring and follow-up of signs of chronic rejection. (Hayes, 2008).

Management of patients with end-stage lung disease and who are waiting for a suitable donor depends on the cause of lung disease. It includes, but is not limited to: (Hachem, 2022; Hayes, 2008).

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

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.

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Pre-Transplant Evaluation

(Connolly, 2022; Weiss, 2022; ¹⁻²MCG, 2021; AST, 2019; Chambers et al., 2018; Raghu et al., 2018; Adegunsoye et al., 2017; Galie et al., 2016; Mehra et al., 2016; Weill et al., 2015; CMS, 2008; Faro et al., 2007; ASTP/ATS/ERS/ISHLT, 1998; SRTR, n.d.)

Please see MCP-323 Pre-Transplant Evaluation for additional criteria and information.

Criteria for transplant evaluation include:

1. History and physical examination; **AND**
2. Psychosocial evaluation and clearance:
 - a. No behavioral health disorder by history or psychosocial issues:
 - If history of behavioral health disorder, no severe psychosis or personality disorder;
 - Mood/anxiety disorder must be excluded or treated;
 - Member has understanding of surgical risk and post procedure compliance and follow-up required.

AND

- b. Adequate family and social support.

AND

3. EKG; **AND**

4. Chest x-ray; **AND**

5. Cardiac clearance in the presence of any of the following:
 - a. Chronic smokers; **OR**
 - b. Members > 50 years age; **OR**
 - c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
 - Normal exam by H&P; **OR**
 - Abnormal neurological exam with positive findings including **ONE** of the following:
 - Lumbar puncture normal cytology; **OR**
 - Lumbar puncture with cytological exam abnormal: CNS disease treated prior to clearance.

AND

8. A Performance Status that includes **ONE** of the following:
 - a. Karnofsky score 70-100%; **OR**
 - b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

AND

9. Lab studies that include:
 - a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
 - b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:***
 - If HIV positive **ALL** of the following must be met:
 - i. CD4 count >200 cells/mm³ for >6 months; **AND**
 - ii. HIV-1 RNA undetectable; **AND**
 - iii. On stable anti-retroviral therapy >3 months; **AND**
 - iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

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- If abnormal serology, need physician plan to address and/or treatment as indicated.
 - i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
 - ii. Ceruloplasmin, α 1-antitrypsin phenotype
 - iii. Alpha-fetoprotein
- c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

10. Colonoscopy (if indicated or if Member is age \geq 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

11. Gynecological examination with Pap smear for women ages \geq 21 to \leq 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or $>$ age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Adult and Pediatric Criteria

(AST, 2019; GOLD, 2019; NICE, 2018; Raghu et al., 2018; Galie et al., 2016; Mehra et al., 2016; Weill et al., 2015; Hayes, 2008; Faro et al., 2007; NICE, 2006; ASTP et al., 1998)

Member must meet **ONE** of the following:

1. Single, double, or donor lobar lung organ transplantation from a deceased or a living donor **is considered medically necessary** in adult and pediatric members when **ALL** of the following criteria are met:
 - a. All pre-transplant criteria are met; **AND**
 - b. Documentation that all medical, pharmaceutical, and surgical alternatives to lung transplant have been utilized if applicable that includes, but is not limited to:
 - Oxygen therapy; **OR**
 - Pulmonary rehabilitation; **OR**
 - Lung volume reduction surgery for patients with chronic obstructive lung disease.

AND

- c. Living Donor lobar lung transplant requests require documentation supporting the Member's inability to survive the wait for a deceased donor allograft:
 - If donor lobar lung transplant is not performed, they may become ineligible for lung transplantation due to clinical deterioration; **OR**
 - Ambulatory with meeting requirements for receiving pulmonary rehab; **OR**
 - End stage pulmonary disease with a life expectancy $<$ 18 months without a transplant; **OR**
 - No other serious systemic disease or condition affecting long term survival; **OR**
 - No documented history of non-compliance.

AND

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- d. For multi-organ heart and lung transplant requests, criteria must be met for each organ requested (see individual policy for heart transplantation criteria); **AND**
- e. The requesting transplant recipient should not have any of the following absolute contraindications:
- Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
 - Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
 - Systemic and/or uncontrolled infection; **OR**
 - AIDS (CD4 count < 200cells/mm³); **OR**
 - Unwilling or unable to follow post-transplant regimen:
 - i. Documented history of non-compliance
 - ii. Inability to follow through with medication adherence or office follow-up

OR

- Chronic illness with one year or less life expectancy; **OR**
- Limited, irreversible rehabilitation potential; **OR**
- Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present; **OR**
- No adequate social/family support.

AND

- f. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
- Smoking, documentation supporting free from smoking for 6 months; **OR**
 - Active peptic ulcer disease; **OR**
 - Active gastroesophageal reflux disease; **OR**
 - CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
 - Obesity with body mass index of >30 kg/m² may increase surgical risk; **OR**
 - Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
 - Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

OR

2. Disease specific criteria as outlined below:

- a. **Chronic Obstructive Lung Disease** (e.g., COPD, emphysema, alpha-1 antitrypsin disease, Bronchiolitis Obliterans Syndrome [BOS], bronchiectasis). Single or double lung transplantation is indicated – guidelines for transplantation include:

- BODE index* score of ≥ 7 measured by a six-minute walk test should be referred for transplant evaluation and **ONE** of the following:
 - i. History of hospitalization for exacerbation of COPD associated with acute hypercapnia (PCO₂ ≥ 50 mmHg); **OR**
 - ii. Three or more severe exacerbations within the preceding year; **OR**
 - iii. Refractory dependence on noninvasive ventilatory assistance; **OR**
 - iv. FEV1 (e.g., forced expiratory volume in the first second) < 20% of predicted, without reversibility; **OR**
 - v. Elevated PaCO₂ >50 mm hg with progressive deterioration requiring long term oxygen therapy (defined as ≥ 6 months); **OR**

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- vi. Moderate to severe pulmonary hypertension (e.g., mean pulmonary artery pressure greater than 35 mm Hg or mean right atrial pressure greater than 15 mm Hg) or cor pulmonale despite oxygen therapy.

* 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%.

- b. **Cystic Fibrosis.** Only double lung transplantation is indicated and guidelines for transplantation include **ANY** of the following:

- Congenital pulmonary disease (e.g., pulmonary hypoplasia, bronchopulmonary dysplasia, surfactant disorders, hereditary hemorrhagic telangiectasia); **OR**
- FEV1 \leq 30% of predicted value; **OR**
- Hypercapnia (defined as PCO₂ \geq 50 mm hg); **OR**
- Increasing frequency of exacerbations requiring cycling antibiotic therapy; **OR**
- Oxygen-dependent respiratory failure; **OR**
- Pulmonary hypertension (mean pulmonary artery pressure > 20 mm hg); **OR**
- Refractory and/or recurrent pneumothorax; **OR**
- Refractory dependence on noninvasive ventilatory assistance; **OR**
- Rapid respiratory deterioration with FEV1 <30% with **ONE** of the following despite medical management:
 - i. Increasing numbers of hospitalizations; **OR**
 - ii. Rapid fall in FEV1; **OR**
 - iii. Exacerbation requiring ICU stay or mechanical ventilation; **OR**
 - iv. Refractory or recurrent pneumothorax; **OR**
 - v. Recurrent hemoptysis not controlled by embolization; **OR**
 - vi. Ongoing weight loss despite aggressive nutritional supplementation.

- c. **Interstitial Lung Disease** (e.g., Idiopathic pulmonary fibrosis (IPF) and Interstitial pneumonia). Single or double lung transplantation is indicated and guidelines for transplantation include:

- Histologic or radiographic evidence of IPF and **ANY** of the following:
 - i. Symptomatic (e.g., oxygen desaturation with rest or exercise), progressive disease with failure to improve or maintain lung function despite standardized optimal therapy (e.g., supplemental oxygen, pulmonary rehabilitation); **OR**
 - ii. A 10% or greater decrease in FVC (i.e., forced vital capacity) during six months of follow-up; **OR**
 - iii. Diffusion capacity for carbon monoxide (DLCO) < 40% of predicted or decline of 15% or more over 6 months; **OR**
 - iv. Extensive reticulation or honeycomb change on CT scan; **OR**
 - v. Pulse oximetry less than 88% or distance less than 250 meters (820 feet) during 6-minute walk test; **OR**
 - vi. Pulmonary hypertension (mean pulmonary artery pressure > 20 mm Hg); **OR**
 - vii. Decrease in 6-minute walk test distance by more than 50 meters (165 feet) over 6 months.

- d. **Sarcoidosis.** Single or double transplantation is indicated and guidelines for transplantation include:

- New York Heart Association (NYHA) functional class III or IV[^] and **ANY** of the following:
 - i. Pulmonary hypertension (mean pulmonary artery pressure > 20 mm Hg); **OR**
 - ii. Hypoxemia at rest (PaO₂ < 55 mm hg); **OR**
 - iii. Right atrial pressure > 15 mm Hg.

- e. **Scleroderma.** Single or double transplantation is indicated and guidelines for transplant include:

- FVC below 70% to 80% predicted at the time of diagnosis.

- f. **Pulmonary Arterial Hypertension (PAH)** (e.g., idiopathic pulmonary hypertension or IPH). Double lung transplantation is preferred and guidelines for transplantation include:

- No feasible pulmonary thromboendarterectomy for patients with chronic pulmonary thromboembolic disease; **AND**
- No successful control of pulmonary arterial hypertension with pharmacogenic agents (e.g., calcium channel blockers or endothelin receptor antagonists); **AND**

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- **ANY** of the following:
 - i. Persistent NYHA functional class III or IV[^] despite maximal medical therapy for 3 months (e.g., combination therapy including prostanoids); **OR**
 - ii. Low (350 meter) six-minute walk test; **OR**
 - iii. Cardiac index < 2 liters per minute per square meter; **OR**
 - iv. Right atrial pressure >15 mm Hg; **OR**
 - v. Mean pulmonary arterial pressure > 20 mm hg; **OR**
 - vi. Refractory right heart failure (progressive renal insufficiency, increasing bilirubin, refractory ascites, increasing brain natriuretic peptide levels).

- g. **Congenital Heart Disease** (e.g., Eisenmenger syndrome). Single or double transplantation is indicated and guidelines for transplant include **ALL** of the following:
 - NYHA functional class III or IV[^]; **AND**
 - Pulmonary hypertension; **AND**
 - Severe progression of symptoms despite optimal medical management (Refer to UpToDate for treatment options for specific indication).

- h. **Pulmonary Langerhans Cell Histiocytosis (PLCH), Lymphangioleiomyomatosis (LAM) and Eosinophilic Granuloma**. Single or double transplantation is indicated – guidelines include:
 - NYHA functional class III or IV[^] and **ANY** of the following:
 - i. Severe impairment in lung function and exercise capacity (VO₂ max < 50%); **OR**
 - ii. Hypoxemia at rest (PaO₂ < 55 mm hg).

- i. **Graft vs host disease** and **ANY** of the following:
 - Progressive lung damage resulting in severe compromise of activities of daily living; **OR**
 - Life expectancy limited by lung disease

- j. **Re-transplantation**. When re-transplantation is considered, **ALL** of the following factors must be present:
 - Member must be ambulatory; **AND**
 - Ventilator independent; **AND**
 - Free of significant co-morbidities; **AND**
 - Meet all other requirements for transplantation outlined above and have **ONE** of these indications:
 - i. Non-function of the grafted organ; **OR**
 - ii. Rejection refractory to immunosuppressive therapy; **OR**
 - iii. Bronchiolitis obliterans (chronic rejection); **OR**
 - iv. Airway complications not correctable by other measures.

NOTE: Requests for third or subsequent lung transplantation may not be authorized.

[^] NYHA Functional Classification is defined as:

I	Patients without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
II	Patients with a slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
III	Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
IV	Patient with the inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

OR

3. For Heart and Lung Transplantation, a simultaneous heart and lung transplantation may be authorized when **ALL** of the following criteria are met:
 - a. Severe refractory end stage heart failure; **AND**
 - b. End-stage lung disease; **OR**
 - c. Irreversible pulmonary hypertension; **AND**
 - d. One of the following conditions:
 - Congenital heart disease with Eisenmenger syndrome; **OR**
 - Cystic fibrosis; **OR**
 - End-stage parenchymal lung disease with severely compromised left ventricular function (e.g., sarcoidosis).

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For Members with Significant or Daily Marijuana Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from marijuana use during the transplant and immediate post-transplant time period. Daily marijuana use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical marijuana use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed marijuana use.
2. If the Member's marijuana use is in compliance with a formal, State-based program for managed medical marijuana, the request should include:
 - Documentation of the Plan of Care for medical marijuana (including the medical decision making that supports the use of medical marijuana); **AND**
 - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical marijuana).

Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
 - a. Presence of no absolute contraindication as listed above; **AND**
 - b. History and physical within the last 12 months; **AND**
 - c. Kidney profile within the last 12 months; **AND**
 - d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.
2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
 - a. Authorization letter/documentation from previous insurer; **AND**
 - b. Presence of no absolute contraindication as listed above; **AND**
 - c. History and physical within the last 12 months; **AND**
 - d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

Limitations and Exclusions

Single, double, or donor lobar lung organ and heart-lung transplantation **is considered not medically necessary** when the above criteria are not met.

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

For peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

National and Specialty Organizations

The following national and specialty organization publications are available on the topic of lung and/or heart transplantation. Links are available in the Reference section.

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

Created in 2001, the GOLD report is recognized worldwide as guidance for providers, specifically the ABCD assessment tool which structures the assessment of COPD symptoms and for the creation of the treatment plan. In addition, the GOLD report includes a review of currently published evidence-based references that can be utilized for the assessment, diagnosis, and treatment of patients with COPD. (GOLD, 2019; Patel et al., 2019). The 2020 update included conditions that should be considered in the differential diagnosis of COPD including pneumonia, pneumothorax, pleural effusion, pulmonary embolism, pulmonary edema due to cardiac related conditions, and cardiac arrhythmias-atrial fibrillation/flutter. Recommendations include the initiations of therapy after a patient demonstrates evidence of a threshold cutoff post-bronchodilator FEV1 to forced vital capacity (FVC) ratio of less than 70%. Exposure and symptoms play an important role and are the physiologic cornerstone of GOLD's definition of COPD however, some patient may have structural changes (e.g., emphysema or significant small airway disease and air trapping and even a reduced FEV1). Patients with a preserved FEV1/FVC ratio are not considered for treatment within the GOLD paradigm. While differences may demonstrate that patients are prone to lung injury due to cigarette smoking or other harmful inhalants, evidence does not support that current treatment option have a significant result on symptoms or progression of disease. (Balkissoon, 2020).

From 2008 to 2011, the COPD Genetic Epidemiology (COPDGene®) study looked at over 10,000 current and former smokers in the United States. Data included baseline evaluations consisting of pre- and post-bronchodilator spirometry, a six-minute walk test, inspiratory and expiratory computed tomography (CT) scans (including a quantitative assessment of airway wall thickness, emphysema, and gas trapping). In addition, individuals completed telephone and web-based follow-up at six-month intervals. A sequence of biomarkers were also collected including fibrinogen C-reactive protein, surfactant protein D, soluble receptor for advanced plication and products, and Clara cell secretory protein. Mortality was also monitored. At five-year follow up, a total of 4615 individuals completed the assessment. Data included information from return visits for physiologic and radiographic assessments (e.g., exposure, symptoms, CT imaging, spirometry, and biomarkers). (Balkissoon, 2020).

International Society for Heart and Lung Transplantation (ISHLT)

The ISHLT published the *Consensus Document for the Selection of Lung Transplant Candidates* (Leard et al., 2021) 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 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 also published the *2016 International Society for Heart Lung Transplantation Listing Criteria for Heart Transplantation: A 10-Year Update*. The document examines updates made regarding congenital heart disease (CHD), restrictive cardiomyopathy, and infectious diseases with respect to transplantation. (Mehra et al., 2016).

American Society of Transplantation (AST)

The AST (2007) published an *Executive Summary on Pediatric Lung Transplantation*. Guidelines were originally published in 1998 regarding the selection of recipients and were developed in partnership with the International Society of Heart and Lung Transplantation (ISHLT) and the American Thoracic Society (ATS). The guidelines include indications for transplantation, general contraindications, timing of referral and evaluation of donor, and post-transplant management of pediatric patients. A section on specific complications is included as well as other considerations such as transition to adult care and growth. The group notes that research is lacking due to the small number of transplants performed overall, making it difficult to perform controlled prospective trials. (Faro et al., 2007).

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American Society for Transplant Physicians (ASTP), American Thoracic Society (ATS), European Respiratory Society (ERS), and International Society for Heart and Lung Transplantation (ISHLT)

The ASTP, ATS, ERS, and ISHLT (1998) published the *International Guidelines for the Selection of Lung Transplant Candidates*. Guidance is provided regarding general indications and criteria for transplantation as well as disease-specific exercise or lung function criteria. A section is included on general medical conditions that impact eligibility for transplantation including contraindications as well as information on diagnostic and prognostic investigations before referral. Disease specific guidelines are also included on the following: COPD, Cystic Fibrosis and other Bronchiectatic Diseases, Idiopathic Pulmonary Fibrosis (Cryptogenic Fibrosing Alveolitis), Pulmonary Hypertension without Congenital Heart Disease, and Pulmonary Hypertension Secondary to Congenital Heart Disease (Eisenmenger's Syndrome). A section is also included for Combined Pulmonary and Other Organ Failure. A section is also included on pediatric lung transplantation.

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 (¹ NICE, 2018). First, referrals should be considered to a multidisciplinary team including lung transplantation specialists for patients who:

- Have severe COPD with FEV1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment; and
- Are non-smokers; and
- Have completed pulmonary rehabilitation; and
- 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. (¹ NICE, 2018). A supplement to the NG115 was published titled *Referral Criteria for Lung Volume Reduction Procedures, Bullectomy or Lung Transplantation* (² NICE, 2018).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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

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HCPCS Codes

HCPCS	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

10/12/2022	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.
9/16/2020	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.
9/15/2016	Policy reviewed, no changes.
6/22/2017	Policy reviewed, no changes.
9/13/2018	Policy reviewed, no changes.
9/18/2019	Policy reviewed, no changes.
4/27/2015	Policy updated with new pretransplant criteria; Summary of Medical Evidence section condensed. Added one new indication for individuals with scleroderma.
8/30/2012	New policy.

REFERENCES

Government Agencies

- Centers for Disease Control and Prevention (CDC). Cystic fibrosis. Available from [CDC](#). Published May 9, 2022. Accessed Sept. 16, 2022.
- Centers for Disease Control and Prevention (CDC). Basics about COPD. Available from [CDC](#). Published June 9, 2021.
- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National Coverage Determination – heart transplants (260.9). Available from [CMS](#). Effective May 1, 2008. Accessed September 13, 2022.
- Scientific Registry of Transplant Recipients (SRTR). National data: Lung transplantation. Available from [here](#). Accessed Sept. 13, 2022.
- World Health Organization (WHO). The top 10 causes of death. Available from [WHO](#). Published Dec. 9, 2020. Accessed Sept. 16, 2022.

Evidence Based Reviews and Publications

- Connolly HM. Management of Eisenmenger syndrome. Available from [UpToDate](#). Updated January 28, 2021. Accessed September 18, 2022. Registration and login required.
- Hachem RR. Lung transplantation: General guidelines for recipient selection. Available from [UpToDate](#). Updated September 8, 2022. Accessed September 18, 2022. Registration and login required.
- Hartwig MG, Klapper JA. Lung transplantation: Procedure and postoperative management. Available from [UpToDate](#). Updated December 10, 2021. Accessed September 18, 2022. Registration and login required.
- Hayes. Living donor lobar lung transplantation. Available from [Hayes](#). Published May 2, 2003. Updated April 14, 2008. Archived November 12, 2008. Accessed September 8, 2022. Registration and login required.
- ¹ MCG. Lung transplant – ORG: S-1300 (ISC), 26th ed. Updated September 1, 2022. Accessed September 13, 2022.
- ² MCG. Lung transplant, pediatric – ORG: P-1300 (ISC), 26th ed. Updated 2021. Accessed September 13, 2022.
- Singer LG, Mooney J. Heart-lung transplantation in adults. Available from [UpToDate](#). Updated January 12, 2022. Accessed September 18, 2022. Registration and login required.
- Weiss ST. Chronic obstructive pulmonary disease: Prognostic factors and comorbid conditions. Available from [UpToDate](#). Updated August 25, 2022. Accessed September 18, 2022. Registration and login required.

National and Specialty Organizations

- American Lung Association. Bronchopulmonary dysplasia Available from [ALA](#). Accessed September 16, 2022. American Society for Transplant Physicians (ASTP) / American Thoracic Society (ATS) / European Respiratory Society (ERS) / International Society for Heart and Lung Transplantation (ISHLT). International guidelines for the selection of lung transplant candidates. Am J Respir Crit Care Med. 1998 Jul;158(1):335-9. doi: 10.1164/ajrccm.158.1.15812. Accessed September 13, 2022.
- Balkissoon R. Journal club – COPD2020 Update. Global Initiative for Chronic Obstructive Lung Disease 2020 report and the Journal of the COPD Foundation Special Edition, Moving to a New Definition for COPD: “COPDGene® 2019”. Chronic Obstr Pulm Dis. 2020; 7(1): 64–72. doi: 10.15326/jcopdf.7.1.2020.0133. Accessed September 13, 2022.

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3. Faro A, Mallory GB, Visner GA, Elidemir O, Mogayzel PJ, et al. American Society of Transplantation executive summary on pediatric lung transplantation. *Am J Transplant*. 2007 Feb;7(2):285-92. doi: 10.1111/j.1600-6143.2006.01612.x. Accessed September 13, 2022.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2019 report. Available from [GOLD](#). Published 2019. Accessed September 13, 2022.
5. Johns Hopkins Medicine. Lung transplant. Available from [Johns Hopkins](#). Accessed September 16, 2022.
6. Leard LE, Holm AM, Valapour M, Glanville AR, Attawar S, Aversa M. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation (Consensus Document) *J Heart Lung Transplant*. 2021 Nov; 40(11):1349-1379. <https://doi.org/10.1016/j.healun.2021.07.005>. Accessed September 13, 2022.
7. Mehra MR, Canter CE, Hannan MM, Semigran MJ, Uber PA, International Society for Heart Lung Transplantation (ISHLT) Infectious Diseases – Pediatric and Heart Failure and Transplantation Councils, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. *J Heart Lung Transplant*. 2016 Jan;35(1):1-23. doi: 10.1016/j.healun.2015.10.023. Accessed September 13, 2022.
8. ¹ National Institute for Health and Clinical Excellence (NICE). Chronic obstructive pulmonary disease in over 16s: Diagnosis and management (NG115). Available from [NICE](#). Published December 5, 2018. Updated July 26, 2019. Accessed September 13, 2022.
9. ² National Institute for Health and Clinical Excellence (NICE). Chronic obstructive pulmonary disease in over 16s: Diagnosis and management – [G] Referral criteria for lung volume reduction procedures, bullectomy or lung transplantation. Available from [NICE](#). Published December 2018. Accessed September 24, 2022.
10. National Organization for Rare Disorders (NORD). Bronchopulmonary dysplasia. Available from [NORD](#). Published 2018. Accessed September 16, 2022.
11. Patel AR, Patel AR, Singh S, Singh S, Khawaja I. Global Initiative for Chronic Obstructive Lung Disease: The changes made. *Cureus*. 2019 Jun 24;11(6):e4985. doi: 10.7759/cureus.4985. Accessed September 13, 2022.

Peer Reviewed Publications

1. Adegunsoye A, Strek ME, Garrity E, Guzy R, Bag R. Comprehensive care of the lung transplant patient. *Chest*. 2017 Jul;152(1):150-164. doi: 10.1016/j.chest.2016.10.001.
2. Chambers DC, Cherikh WS, Goldfarb SB, et al. The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Thirty-fifth adult lung and heart-lung transplant report – 2018; Focus theme: Multiorgan Transplantation. *J Heart Lung Transplant*. 2018 Oct;37(10):1155-1168. doi: 10.1016/j.healun.2018.07.022.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

Chronic Obstructive Lung Disease

1. Cheronis N, Rabold E, Singh A, Cheema T. Lung Transplantation in COPD. *Crit Care Nurs Q*. 2021 Jan/Mar;44(1):61-73. doi: 10.1097/CNQ.0000000000000340. Accessed September 24, 2022.
2. Greer M, Welte T. Chronic obstructive pulmonary disease and lung transplantation. *Semin Respir Crit Care Med*. 2020 Dec;41(6):862-873. doi: 10.1055/s-0040-1714250. Accessed September 24, 2022.
3. Lane CR, Tonelli AR. Lung transplantation in chronic obstructive pulmonary disease: patient selection and special considerations. *Int J Chron Obstruct Pulmon Dis*. 2015 Oct 9;10:2137-46. doi: 10.2147/COPD.S78677. Accessed September 24, 2022.
4. Schulman LL. Lung transplantation for chronic obstructive pulmonary disease. *Clin Chest Med*. 2000 Dec;21(4):849-65. doi: 10.1016/s0272-5231(05)70187-8. Accessed September 24, 2022.
5. Siddiqui FM, Diamond JM. Lung Transplantation for Chronic Obstructive Pulmonary Disease: past, present, and future directions. *Curr Opin Pulm Med*. 2018 Mar; 24(2): 199–204. doi: 10.1097/MCP.0000000000000452. Accessed September 24, 2022.

Cystic Fibrosis

6. Jardel S, Reynaud Q, Durieu I. Long-term extrapulmonary comorbidities after lung transplantation in cystic fibrosis: Update of specificities. *Clin Transplant*. 2018 Jun;32(6):e13269. doi: 10.1111/ctr.13269. Accessed September 24, 2022.
7. Morrell MR, Pilewski JM. Lung transplantation for cystic fibrosis. *Clin Chest Med*. 2016 Mar;37(1):127-38. doi: 10.1016/j.ccm.2015.11.008. Accessed September 24, 2022.
8. Ramos KJ, Smith PJ, McKone EF, Pilewski JM, Lucy A, CF Lung Transplant Referral Guidelines Committee, et al. Lung transplant referral for individuals with cystic fibrosis: Cystic Fibrosis Foundation consensus guidelines. *J Cyst Fibros*. 2019 May;18(3):321-333. doi: 10.1016/j.jcf.2019.03.002. Accessed September 24, 2022.
9. Snell G, Reed A, Stern M, Hadjiliadis D. The evolution of lung transplantation for cystic fibrosis: A 2017 update. *J Cyst Fibros*. 2017 Sep;16(5):553-564. doi: 10.1016/j.jcf.2017.06.008. Accessed September 24, 2022.
10. Yeung JC, Machuca TN, Chaparro C, Cypel M, Stephenson AL, Solomon M, et al. Lung transplantation for cystic fibrosis. *J Heart Lung Transplant*. 2020 Jun;39(6):553-560. doi: 10.1016/j.healun.2020.02.010. Accessed September 24, 2022.

Interstitial Lung Disease

11. Kapnadak SG, Raghu G. Lung transplantation for interstitial lung disease. *Eur Respir Rev*. 2021 Aug 3;30(161):210017. doi: 10.1183/16000617.0017-2021. Accessed September 24, 2022.

Lung Transplantation

12. Lorrana E Leard 1, Are M Holm 2, Maryam Valapour 3, Allan R Glanville 4, Sandeep Attawar 5, Meghan Aversa
13. Meyer KC. Recent advances in lung transplantation. *F1000Res*. 2018 Oct 23;7:F1000 Faculty Rev-1684. doi: 10.12688/f1000research.15393.1. Accessed September 24, 2022.
14. Yeung JC, Keshavjee S. Overview of clinical lung transplantation. *Cold Spring Harb Perspect Med*. 2014 Jan; 4(1): a015628. doi: 10.1101/cshperspect.a015628. Accessed September 24, 2022.
15. Young KA, Dilling DF. The future of lung transplantation. *Chest*. 2019 Mar;155(3):465-473. doi: 10.1016/j.chest.2018.08.1036. Accessed September 24, 2022.

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Sarcoidosis

16. Le Pavec J, Valeyre D, Gazengel P, Holm AM, Schultz HH, Perch M, et al. Lung transplantation for sarcoidosis: outcome and prognostic factors. *Eur Respir J*. 2021 Aug 5;58(2):2003358. doi: 10.1183/13993003.03358-2020. Accessed Sept. 24, 2022.
17. Meyer KC. Lung transplantation for pulmonary sarcoidosis. *Sarcoidosis Vasc Diffuse Lung Dis*. 2019;36(2):92-107. doi: 10.36141/svdlld.v36i2.7163. Accessed September 24, 2022.
18. Shah L. Lung transplantation in sarcoidosis. *Semin Respir Crit Care Med*. 2007 Feb;28(1):134-40. doi: 10.1055/s-2007-970339. Accessed September 24, 2022.

Scleroderma

19. Jablonski R, Dematte J, Bhorade S. Lung transplantation in scleroderma: recent advances and lessons. *Curr Opin Rheumatol*. 2018 Nov;30(6):562-569. doi: 10.1097/BOR.0000000000000546. Accessed September 24, 2022.
20. Pradère P, Tudorache I, Magnusson J, Savale L, Brugiére O, Working Group on Heart/Lung Transplantation in Systemic Sclerosis, et al. Lung transplantation for scleroderma lung disease: An international, multicenter, observational cohort study. *J Heart Lung Transplant*. 2018 Jul;37(7):903-911. doi: 10.1016/j.healun.2018.03.003. Accessed September 24, 2022.
21. Sehgal S, Pennington KM, Zhao H, Kennedy CC. Lung transplantation in systemic sclerosis: A practice survey of United States lung transplant centers. *Transplant Direct*. 2021 Sep 7;7(10):e757. doi: 10.1097/TXD.0000000000001209. Accessed September 24, 2022.

Pulmonary Arterial Hypertension (PAH)

22. Schwarz S, Benazzo A, Prosch H, Jaksch P, Klepetko W, Hoetzenecker K, Vienna Lung Transplant Group. Lung transplantation for pulmonary hypertension with giant pulmonary artery aneurysm. *J Thorac Cardiovasc Surg*. 2020 Jun;159(6):2543-2550. doi: 10.1016/j.jtcvs.2019.09.178. Accessed September 24, 2022.
23. Sultan S, Tseng S, Stanziola AA, Hodges T, Saggarr R, Saggarr R. Pulmonary hypertension: The role of lung transplantation. *Heart Fail Clin*. 2018 Jul;14(3):327-331. doi: 10.1016/j.hfc.2018.02.007. Accessed September 24, 2022.

Re-Transplantation

24. Halloran K, Aversa M, Tinckam K, Martinu T, Binnie M, Chaparro C, et al. Comprehensive outcomes after lung retransplantation: A single-center review. *Clin Transplant*. 2018 Jun;32(6):e13281. doi: 10.1111/ctr.13281. Accessed September 24, 2022.
25. Michel E, Hartwig MG, Sommer W. Lung retransplantation. *Thorac Surg Clin*. 2022 May;32(2):259-268. doi: 10.1016/j.thorsurg.2021.12.001. Accessed September 24, 2022.
26. Ren D, Kaleekal TS, Graviss EA, Nguyen DT, Sinha N, Goodarzi A, et al. Retransplantation outcomes at a large lung transplantation program. *Transplant Direct*. 2018 Oct 25;4(11):e404. doi: 10.1097/TXD.0000000000000844. Accessed September 24, 2022.
27. Rucker AJ, Nellis JR, Klapper JA, Hartwig MG. Lung retransplantation in the modern era. *J Thorac Dis*. 2021 Nov;13(11):6587-6593. doi: 10.21037/jtd-2021-25. Accessed September 24, 2022.

APPENDIX

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