

# Molina Clinical Policy

## Lung Transplantation: Policy No. 115

Last Approval: 10/13/2021

Next Review Due By: October 2022



### 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.<sup>1</sup> References included were accurate at the time of policy approval and publication.

### OVERVIEW

Lung transplantation is a surgical procedure to replace one or both diseased lungs with a healthy lung or lungs from a donor. There are different types of lung transplantation, including a lobe transplant, a single lung transplant, a double lung transplant, or a heart-lung transplant. Lung transplantation has become a viable treatment option for selected patients with end-stage lung disease due to a wide variety of underlying disorders. Single, double, and lobar-lung transplantation have all been performed successfully. Living donor lobar lung transplantation has shown success and addresses the shortage of cadaveric organs. 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 and 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.<sup>5,6</sup>

A heart-lung transplant is a procedure where the transplantation of one or both lungs and heart from a single cadaver donor is done. 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 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.<sup>7</sup>

**Single Lung Transplantation.** The operation begins when the donor lung arrives in the operating room. A single lung transplant requires 4 to 8 hours. 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, because that avoids having to maneuver around the heart, as would be 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. When the surgeon is satisfied with the performance of the lung, the chest incision is closed. Single lung transplants are most commonly performed in patients with idiopathic pulmonary fibrosis.<sup>8</sup>

**Double Lung Transplantation.** A double lung transplant, also known as a bilateral transplant, can be performed sequentially, en bloc, or simultaneously. The most frequently performed double lung transplantation procedure is bilateral sequential single lung transplantation. The procedure requires 6 to 12 hours. For double lung transplants, an incision, known as 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

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described for single lung transplantation. Removal of both lungs is mandatory in patients with end stage cystic fibrosis therefore double lung transplants are preferred. In patients with pulmonary artery hypertension double lung transplantation is preferred.<sup>8</sup>

**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. The objectives of the surgery are to improve functional status and quality of life and 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. The majority of living donor lung recipients are patients with cystic fibrosis and the majority of 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.<sup>9</sup>

**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.<sup>9</sup>

Management of patients who have 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:<sup>8,9</sup>

- 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 1-4,10-23,25-27

**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.**

**Members must meet United Network for Organ Sharing (UNOS) / Organ Procurement and Transplantation**

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**Network (OPTN) policies and guidelines for pre-transplantation evaluation and listing criteria and the diagnosis must be made by a specialist in the disease and/or a Transplant Surgeon.<sup>2,3</sup>**

**Pre-Transplant Evaluation**

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

Criteria for transplant evaluation include **ALL** of the following:

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. Pulmonary Function Tests; **AND**
8. 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/mm<sup>3</sup> 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).
    - If abnormal serology, need physician plan to address and/or treatment as indicated.
  - c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

**AND**

9. 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).\*

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**AND**

10. 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** <sup>6,9,14-23</sup>

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 (Refer to *MCP-086: Pulmonary Rehabilitation for Chronic Pulmonary Diseases*); **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**

- 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/mm<sup>3</sup>); **OR**
  - Unwilling or unable to follow post-transplant regimen:
    - i. Documented history of non-compliance

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- 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  $>30 \text{ kg/m}^2$  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:<sup>6,9,14-23</sup>

- 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  $\geq 7$  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 ( $\text{PCO}_2 \geq 50 \text{ mmHg}$ ); **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;
  - v. elevated  $\text{PaCO}_2 > 50 \text{ mm hg}$  with progressive deterioration requiring long term oxygen therapy (defined as  $\geq 6$  months); **OR**
  - vi. Moderate to severe pulmonary hypertension (e.g., mean pulmonary artery pressure greater than  $35 \text{ mm Hg}$  or mean right atrial pressure greater than  $15 \text{ mm Hg}$ ) 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 4 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**
- $\text{FEV1} \leq 30\%$  of predicted value; **OR**
- Hypercapnia (defined as  $\text{PCO}_2 \geq 50 \text{ mm hg}$ ); **OR**
- Increasing frequency of exacerbations requiring cycling antibiotic therapy; **OR**
- Oxygen-dependent respiratory failure; **OR**

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- 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<sup>^</sup> and **ANY** of the following:
    - i. Pulmonary hypertension (mean pulmonary artery pressure > 20 mm Hg); **OR**
    - ii. Hypoxemia at rest (PaO<sub>2</sub> < 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**
  - **ANY** of the following:
    - i. Persistent NYHA functional class III or IV<sup>^</sup> despite maximal medical therapy for 3 months (eg, 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:<sup>29</sup>
- NYHA functional class III or IV<sup>^</sup>; **AND**
  - Pulmonary hypertension; **AND**

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- 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<sup>^</sup> and **ANY** of the following:
    - i. Severe impairment in lung function and exercise capacity (VO<sub>2</sub> max < 50%); **OR**
    - ii. Hypoxemia at rest (PaO<sub>2</sub> < 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.**

<sup>^</sup> NYHA Functional Classification is defined as:

<b>I</b>	Patients without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
<b>II</b>	Patients with a slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
<b>III</b>	Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
<b>IV</b>	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;<sup>29</sup> **OR**
    - Cystic fibrosis; **OR**
    - End-stage parenchymal lung disease with severely compromised left ventricular function (e.g., sarcoidosis).

**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**

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- d. Cardiac update if history of cardiac disease within two years ( $\geq 50$  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 ( $\geq 50$  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**

The published medical evidence and outcomes for lung and heart-lung transplantation in children and adults in the United States consists of registry data obtained from transplant centers that perform adult and pediatric transplantation and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.<sup>2-4,24</sup>

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.

- **American Society for Transplant Physicians (ASTP), American Thoracic Society (ATS), European Respiratory Society (ERS), and International Society for Heart and Lung Transplantation (ISHLT) – International Guidelines for the Selection of Lung Transplant Candidates**<sup>14</sup>
- **American Society of Transplantation (AST) – Transplant Infectious Disease Guidelines (4th ed.)**<sup>15</sup>
- **American Society of Transplantation – Executive Summary on Pediatric Lung Transplantation**<sup>16</sup>
- **International Society for Heart Lung Transplantation – Listing Criteria: A 10-Year Update**<sup>17</sup>
- **International Society for Heart and Lung Transplantation – A Consensus Document for the Selection of Lung Transplant Candidates: 2014 Update from the Pulmonary Transplantation Council**<sup>18</sup>
- **National Institute for Health and Clinical Excellence (NICE) – Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management (NG115)**<sup>19</sup>
- **National Institute for Health and Clinical Excellence (NICE) – Living Donor Lung Transplantation for End-Stage Lung Disease (IPG no. 170)**<sup>20</sup>
- **Global Initiative for Chronic Obstructive Lung Disease (GOLD) – Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2020 Report**<sup>21</sup>
- **American Thoracic Society (ATS), European Respiratory Society (ERS), Japanese Respiratory Society (JRS), and Latin American Thoracic Society (LATS) – Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline**<sup>22</sup>
- **European Society of Cardiology (ESC) and European Respiratory Society (ERS) – ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension**<sup>23</sup>



## 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

### 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

<b>10/13/2021</b>	Policy reviewed, no criteria updates, updated references. Coding section updated; removed CPT codes 33930, 33933, 33935.
<b>9/16/2020</b>	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.
<b>9/15/2016</b>	Policy reviewed, no changes.
<b>6/22/2017</b>	Policy reviewed, no changes.
<b>9/13/2018</b>	Policy reviewed, no changes.
<b>9/18/2019</b>	Policy reviewed, no changes.
<b>4/27/2015</b>	Policy updated with new pretransplant criteria; Summary of Medical Evidence section condensed. Added one new indication for individuals with scleroderma.
<b>8/30/2012</b>	New policy.

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# Molina Clinical Policy

## Lung Transplantation: Policy No. 115

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## APPENDIX

*Reserved for State specific information (to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*