

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.007.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

PA.007.MH – Transplant: Lung and Lobar Lung

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Lung and Lobar Lung Transplants** medically necessary for the following indications:

Recipient Characteristics

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

GENERAL CRITERIA for Lung and Lobar Lung Transplant

General Criteria:

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

DISEASE SPECIFIC CRITERIA

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

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

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH

Last Review Date: 08/26/2021

Effective Date: 10/01/2021

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

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

Pulmonary fibrosis associated with collagen vascular diseases:

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

Sarcoidosis:

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

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

- Patients with a BODE index of 7-10 or at least one of the following:
 - a) History of hospitalization(s) within the past year for exacerbation associated with hypercapnea and pCO₂ > 50mmHg
 - b) Refractory cor pulmonale and/or pulmonary hypertension despite oxygen therapy
 - c) FEV₁ < 20% predicted and DLCO < 20% predicted or homogenous distribution of emphysema

Pulmonary arterial hypertension:

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

Cystic Fibrosis and other causes of Bronchiectasis:

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

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

- And all of the following:
 1. Oxygen-dependent respiratory failure
 2. Hypercapnea
 3. Pulmonary hypertension

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

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

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

Limitations

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

Background

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

- **Pulmonary vascular disease:**
 - Primary pulmonary hypertension
 - Eisenmenger's syndrome or complex
 - Pulmonary hypertension secondary to thromboembolic disease
 - Cardiomyopathy with pulmonary hypertension
- **Obstructive lung disease:**
 - Emphysema – idiopathic

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

- Emphysema – alpha (1) antitrypsin deficiency
- Cystic Fibrosis
- Bronchiectasis
- Chronic Obstructive Pulmonary Disease (COPD)
- **Restrictive lung disease:**
 - Idiopathic pulmonary fibrosis
 - Interstitial pulmonary fibrosis
 - Sarcoidosis
 - Asbestosis
- **Subsequent operation for failure of original graft**

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

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

- FEV1 % Predicted After Bronchodialator
 - $\geq 65\%$ (0 points)
 - 50-64% (1 point)
 - 36-49% (2 points)
 - $\leq 35\%$ (3 points)
- 6 Minute Walk Distance
 - ≥ 350 Meters (0 points)
 - 250-349 Meters (1 point)
 - 150-249 Meters (2 points)
 - ≤ 149 Meters (3 points)
- Modified Medical Research Council Scale (MMRC) Dyspnea Scale
 - MMRC 0: Dyspneic on strenuous exercise (0 points)
 - MMRC 1: Dyspneic on walking a slight hill (0 points)
 - MMRC 2: Dyspneic on walking level ground; must stop occasionally due to breathlessness (1 point)
 - MMRC 3: Must stop for breathlessness after walking 100 yards or after a few minutes (2 points)
 - MMRC 4: Cannot leave house; breathless on dressing/undressing (3 points)
- Body Mass Index
 - >21 (0 points)
 - ≤ 21 (1 point)

Approximate 4 Year Survival Interpretation:

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

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

New York Heart Association (NYHA) Functional Classification:

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

Codes:

CPT/HCPCS Codes	
Code	Description
32851	Lung transplant, single
32852	Lung transplant, single; with bypass
32853	Lung transplant, double
32854	Lung transplant, double; with bypass
32855	Backbench preparation of cadaver donor lung; unilateral
32856	Backbench preparation of cadaver donor lung; bilateral
S2060	Lobar lung transplant

References

1. American College of Chest Physicians. A Guide to Lung Transplantation. Patient Education Guide. 2006.
https://www.lungeninformationsdienst.de/fileadmin/LUNGENINFO/Therapie/Lung_Transplantation_4_.pdf
2. American Heart Association – Classes of Heart Failure. Updated April 23, 2015.
<https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure>
3. American Society of Transplantation: Facts about Lung Transplants, Revised 12/2006. https://www.myast.org/sites/default/files/pdfs/getting_new_lung_0.pdf
4. American Thoracic Society. International guidelines for the selection of lung transplant candidates. Am J Respir Crit Care Med. 1998; 158(1):335-339.
<http://www.atsjournals.org/doi/pdf/10.1164/ajrccm.158.1.15812>

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH

Last Review Date: 08/26/2021

Effective Date: 10/01/2021

5. Arcasoy SM, Kotloff RM. Medical Progress: Lung transplantation. *N Engl J Med*. 1999; 340(14):1081-1091.
<http://www.nejm.org/doi/full/10.1056/NEJM199904083401406>
6. Bhagani S, Sweny PI, Brook G. Guidelines for kidney transplantation in patients with HIV disease. *HIV Med* 2006 Apr; 7(3):133-139.
<https://pubmed.ncbi.nlm.nih.gov/16494626/>
7. BODE Index for COPD Survival Prediction.
<http://reference.medscape.com/calculator/bode-index-copd>
8. Celli BR, Cote CG, Marin JM, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med*. 2004 Mar; 350:1005-1012.
<http://www.nejm.org/doi/full/10.1056/NEJMoa021322>
9. Centers for Disease Control and Prevention (CDC). About HIV/AIDS. Last modified: Jan. 16, 2015. <http://www.cdc.gov/hiv/basics/whatishiv.html>
10. Centers for Medicare and Medicaid Services: National Coverage Determination 260.9-heart transplants, effective 5/1/2008. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=112&ncdver=3&DocID=260.9&SearchType=Advanced&bc=IAAAAAGAAAAAA%3d%3d#>
11. DeMeo DL, Ginns LC: Lung transplantation at the turn of the century. *Annu Rev Med*. 2001; 52:185-201. <https://pubmed.ncbi.nlm.nih.gov/11160774/>
12. Green, I.: Institutional & Patient Criteria for Heart Lung Transplantation. Health Technology Assessment No.1. AHCPR Pub. 94-0042, Rockville MD. May 1994.
<http://www.ncbi.nlm.nih.gov/books/NBK63984/?report=reader>
13. Grover, FL, Fullerton, DA, Zamora Mr, et al.: The past, present, and future of lung transplantation. *Am J Surg*. 1997 Jun; 173(6):523-533.
<http://www.ncbi.nlm.nih.gov/pubmed/9207168>
14. Halpern SD, Ubel PA, Caplan AL. Solid organ transplantation in HIV-infected patients. *N Engl J Med*. 2002 July; 347(4):284-287.
<http://www.nejm.org/doi/pdf/10.1056/NEJMsb020632>
15. Hachem RR (Trulock E, ed.) Lung transplantation: Disease-based choice of procedure. UpToDate®. Mar. 30, 2015. Topic 4660 Version 10.0.
<http://www.uptodate.com/contents/lung-transplantation-disease-based-choice-of-procedure?topicKey=PULM%2F4660&elapsedTimeMs=4&view=print&displayedView=full#>
16. Kaiser Family Foundation. Global Health Reporting. AIDS 2010: The double-edged sword: Long-term complications of ART and HIV July 19, 2010. [video presentation] <http://kff.org/global-health-policy/event/aids-2010-the-double-edged-sword-long-term-complications-of-art-and-hiv/>
17. Kreider, M., et al. (2011). "Candidate selection, timing of listing, and choice of procedure for lung transplantation." *Clin Chest Med* 32(2): 199-211.

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH

Last Review Date: 08/26/2021

Effective Date: 10/01/2021

https://neuro.unboundmedicine.com/medline/citation/21511083/Candidate_selection_timing_of_listing_and_choice_of_procedure_for_lung_transplantation

18. Kreider, M. and R. M. Kotloff (2009). "Selection of candidates for lung transplantation." Proc Am Thorac Soc 6(1): 20-27, <https://pubmed.ncbi.nlm.nih.gov/19131527/>
19. Orens JB Estenne M, Arcasoy S, et al. International guidelines for the selection of lung transplant candidates: 2006 update—A consensus report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant., 2006 July; 25(7):745-755. <http://www.ncbi.nlm.nih.gov/pubmed/16818116>
20. Peters, SG, McDougall, JC, Scott JP, et al.: Lung transplantation: selection of patients and analysis of outcome. Mayo Clin Proc. 1997 Jan; 72(1):85 -88. http://www.atsjournals.org/doi/full/10.1513/pats.200808-097GO#.V5ZIX_krLIU
21. Roland ME, Stock PG. Solid organ transplantation is a reality for patients with HIV infection. Curr HIV/AIDS Rep. 2006 Sep; 3(3):132-138. <http://www.ncbi.nlm.nih.gov/pubmed/16970840>
22. SRTR & OPTN Annual Data Report 2012. http://srtr.transplant.hrsa.gov/annual_reports/2012/pdf/06_lung_13.pdf
23. Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May. 71(9):1189-1204. <http://www.ncbi.nlm.nih.gov/pubmed/11397947>
24. Stock PG, Roland ME.: Evolving clinical strategies for transplantation in the HIV-positive recipient. Transplantation 2007; 84: 563-571. <http://www.hemophilia.ca/files/Stock%20and%20Roland%20September%202007.pdf>
25. Trulock EP. Chapter 266: Lung Transplantation. In: Longo DI, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, eds. Harrison's Principles of Internal Medicine. 18th ed. New York: McGraw-Hill; 2012. <http://accessmedicine.com/content.aspx?aid=9129267>

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary,

PA.007.MH – Transplant: Lung and Lobar Lung

Policy Number: PA.007.MH

Last Review Date: 08/26/2021

Effective Date: 10/01/2021

shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.