MASSACHUSETTS

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Medical Policy

Lung and Lobar Lung Transplant

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Policy Number: 015

BCBSA Reference Number: 7.03.07 (For Plan internal use only)
NCD/LCD: NA

Related Policies

- Heart/Lung Transplant, #269
- Outpatient Pulmonary Rehabilitation, #136

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Lung transplantation may be considered **MEDICALLY NECESSARY** for carefully selected individuals with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy.

Lobar lung transplant from a living or deceased donor may be considered **MEDICALLY NECESSARY** for carefully selected individuals with end-stage pulmonary disease.

Etiologies of End-Stage Lung Disease

- Bilateral bronchiectasis
- Alpha-1 antitrypsin deficiency
- Primary pulmonary hypertension
- Cystic fibrosis (both lungs to be transplanted)
- Bronchopulmonary dysplasia
- Postinflammatory pulmonary fibrosis
- Idiopathic/interstitial pulmonary fibrosis
- Sarcoidosis
- Scleroderma
- Lymphangiomyomatosis
- Emphysema
- Eosinophilic granuloma
- Bronchiolitis obliterans

- Recurrent pulmonary embolism
- Pulmonary hypertension due to cardiac disease
- Chronic obstructive pulmonary disease
- Eisenmenger's syndrome.

Lung or lobar lung transplants in individuals with any of the following conditions are **NOT MEDICALLY NECESSARY**:

1. Known active malignancy, including metastatic cancer
2. Recently treated malignancy with a high risk of recurrence
   Note: *the assessment of risk of recurrence of a recently treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.*
3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to lung disease
5. History of cancer with a moderate risk of recurrence
6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependence affecting the ability to adhere to therapy
8. Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function, or
9. Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

Lung or lobar lung retransplantation after a failed lung or lobar lung transplant may be considered **MEDICALLY NECESSARY** in patients who meet criteria for lung transplantation.

Lung or lobar lung transplantation is considered **INVESTIGATIONAL** in all other situations.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.
Medicare HMO Blue℠	This procedure is performed in the inpatient setting.
Medicare PPO Blue℠	This procedure is performed in the inpatient setting.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass

HCPCS Codes

HCPCS codes:	Code Description
S2060	Lobar lung transplantation

ICD-10 Procedure Codes

ICD-10-CM Diagnosis codes:	Code Description
0BYC0Z0	Transplantation of Right Upper Lung Lobe, Allogeneic, Open Approach
0BYC0Z1	Transplantation of Right Upper Lung Lobe, Syngeneic, Open Approach
0BYD0Z0	Transplantation of Right Middle Lung Lobe, Allogeneic, Open Approach
0BYD0Z1	Transplantation of Right Middle Lung Lobe, Syngeneic, Open Approach
0BYF0Z0	Transplantation of Right Lower Lung Lobe, Allogeneic, Open Approach
0BYF0Z1	Transplantation of Right Lower Lung Lobe, Syngeneic, Open Approach
0BYG0Z0	Transplantation of Left Upper Lung Lobe, Allogeneic, Open Approach
0BYG0Z1	Transplantation of Left Upper Lung Lobe, Syngeneic, Open Approach
0BYH0Z0	Transplantation of Lung Lingula, Allogeneic, Open Approach
0BYH0Z1	Transplantation of Lung Lingula, Syngeneic, Open Approach
0BYJ0Z0	Transplantation of Left Lower Lung Lobe, Allogeneic, Open Approach
0BYJ0Z1	Transplantation of Left Lower Lung Lobe, Syngeneic, Open Approach
0BYK0Z0	Transplantation of Right Lung, Allogeneic, Open Approach
0BYK0Z1	Transplantation of Right Lung, Syngeneic, Open Approach
0BYL0Z0	Transplantation of Left Lung, Allogeneic, Open Approach
0BYL0Z1	Transplantation of Left Lung, Syngeneic, Open Approach
0BYM0Z0	Transplantation of Bilateral Lungs, Allogeneic, Open Approach
0BYM0Z1	Transplantation of Bilateral Lungs, Syngeneic, Open Approach

DESCRIPTION

Solid organ transplantation offers a treatment option for patients with different types of endstage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life.[1,] Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing.

Lung Transplant

In 2022 , 42,880 transplants were performed in the United States procured from more than 14,900 deceased donors and 6,400 living donors.[2,] Lung transplants were the fourth most common procedure with 2,692 transplants performed from both deceased and living donors in 2022.

End-stage lung disease may derive from different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, a1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. Before consideration for transplant, patients should be receiving maximal medical therapy, including oxygen supplementation, or surgical options, such as lung volume reduction surgery for chronic obstructive pulmonary disease. Lung or lobar lung transplantation is an option for patients with end-stage lung disease despite these measures.

A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only 1 lung from a deceased donor is provided to the recipient. In a double-lung transplant, both the recipient's lungs are removed and replaced by the donor's lungs. In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions, and transplanted. Donors for lobar transplant have primarily been living-related donors, with 1 lobe obtained from each of 2 donors (generally friends or family members) in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants.

Potential recipients who are 12 years of age and older are ranked according to the Lung Allocation Score.[3] A score may range between 0 and 100 and incorporates predicted survival after transplantation and predicted survival on the waiting list; the Lung Allocation Score takes into consideration the patient's disease and clinical parameters. The waiting list incorporates the Lung Allocation Score, geography, and blood type classifications. Children younger than 12 years old receive priority for lung allocation. Under this system, children younger than 12 years old with respiratory lung failure and/or pulmonary hypertension who meet criteria are considered "priority 1", and all other candidates in the age group are considered "priority 2". A lung review board has the authority to adjust scores on appeal for adults and children.

Potential Contraindications to Transplantation

Malignancy

Malignancies are common after lung transplantation, with 21% and 40% of patients reporting 1 or more malignancies at 5 and 10 years posttransplantation, respectively.[4] Skin cancer occurred most frequently, and lymphoproliferative disorders were the malignancies most associated with morbidity posttransplantation.

Human Immunodeficiency Virus Infection

Current OPTN policy permits human immunodeficiency virus (HIV)-positive transplant candidates. The 2020 US Public Health Service guideline also allows for transplantations in HIV-positive recipients with proper screenings and effective regimens for HIV infections; it recommended that all transplant candidates receive HIV, hepatitis b virus (HBV), and hepatitis C virus (HCV) testing during hospital admission for transplant surgery.[5] In 2022, the US Public Health Service published updated guidance for testing transplant candidates aged less than 12 years of age. [6] They recommended that children less than 12 years of age who have received postnatal infectious disease testing are exempt from repeat pretransplant HIV, HBV, and HCV testing during hospital admission for transplant surgery.

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease.[7] These criteria for adding a patient to the waitlist may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy
- Cluster of Differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- No opportunistic infections for at least 6 months
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

Other Infections

Infection with Burkholderia cenocepacia is associated with increased mortality in some transplant centers, a factor that may be considered when evaluating the overall risk of transplant survival.[8,] Two articles have evaluated the impact of infection with various species of Burkholderia on outcomes for lung transplantation for cystic fibrosis. In a study by Murray et al (2008), multivariate Cox survival models were applied to 1026 lung transplant candidates and 528 transplant recipients.[9,] Of the transplant recipients, 88 were infected with Burkholderia. Among transplant recipients infected with B. cenocepacia, only those infected with nonepidemic strains (n=11) had significantly greater posttransplant mortality than uninfected patients (hazard ratio [HR] , 2.52; 95% confidence interval [CI], 1.04 to 6.12; p=.04). Transplant recipients infected with Burkholderia gladioli (n=14) also had significantly greater posttransplant mortality than uninfected patients (HR , 2.23; 95% CI, 1.05 to 4.74; p=.04). When adjustments for specific species or strains were included, the Lung Allocation Scores of Burkholderia multivorans-infected transplant candidates were comparable with uninfected candidate scores, and scores for patients infected with nonepidemic B. cenocepacia or B. gladioli were lower. In a smaller study of 22 patients colonized with Burkholderia cepacia complex who underwent lung transplantation in 2 French centers, Boussaud et al (2008) reported that the risk of death by univariate analysis was significantly higher for the 8 patients infected with B. cenocepacia than for the other 14 colonized patients (11 of whom had B. multivorans).[10,]

An analysis of international registry data by Yusen et al (2016) found that non-cytomegalovirus (CMV) infection is a major cause of mortality within 30 days of a lung transplant in adults.[11,] A total of 655 (19%) of 3424 deaths after transplants between 1990 and 2015 were due to non-CMV infection. Only 3 (0.1%) of the deaths were due to CMV infection.

Summary

A lung transplant consists of replacing all or part of diseased lungs with healthy lung(s) or lobes. Transplantation is an option for patients with end-stage lung disease.

Summary of Evidence

For individuals who have end-stage pulmonary disease who receive a lung transplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival (OS), change in disease status, and treatment-related mortality and morbidity. International registry data on a large number of patients receiving lung transplantation (>50,000) found relatively high patient survival rates, especially among those who survived the first year posttransplant. After adjusting for potential confounding factors, survival did not differ significantly after single- or double-lung transplant. Lung transplantation may be the only option for some patients with end-stage lung disease. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have end-stage pulmonary disease who receive a lobar lung transplant, the evidence includes case series and systematic reviews. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. There are less data on lung lobar transplants than on whole-lung transplants, but several case series have reported reasonably similar survival outcomes between the procedures, and lung lobar transplants may be the only option for patients unable to wait for a whole-lung transplant. A 2017 systematic review found 1-year survival rates in available published studies ranging from 50% to 100%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a prior lung or lobar transplant who meet criteria for a lung transplant and receive a lung or lobar lung retransplant, the evidence includes case series and registry studies. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from registries and case series have found favorable outcomes with lung retransplantation in patients who meet criteria for initial lung transplantation. Given the exceedingly poor survival prognosis without retransplantation of patients who have exhausted other treatments, the evidence of a moderate level of posttransplant survival may be considered sufficient in this patient population. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
10/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2022	Annual policy review. references added. Minor editorial refinements to policy statements; intent unchanged.
9/2021	Annual policy review. Policy statements unchanged.
10/2020	Annual policy review. Description, summary, and references updated. Policy statement(s) unchanged.
10/2019	Annual policy review. Description, summary, and references updated. Policy statement(s) unchanged.
10/2018	Annual policy review. Description, summary, and references updated. Policy statement(s) unchanged.
10/2018	Annual policy review. No changes to policy statements. New references added. Summary clarified.
1/2018	Clarified coding information.
10/2017	Annual policy review. Conditions for covered indications moved to Policy Guidelines. 10/1/2017
8/2015	Added coding language.
3/2015	Annual policy review. New references added
10/2014	Coding information clarified.
6/2014	Annual policy review. New medically necessary and investigational indications described. Effective 6/1/2014.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
12/2013	Removed ICD-9 diagnosis codes as the policy requires prior authorization
6/2013	Annual policy review. In lobar lung statement, “children and adolescents” replaced with “carefully selected patients.” Effective 6/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group – GI, Nutrition and Organ Transplantation. No changes to policy statements.
3/2011	Annual policy review. Changes to policy statement.
11/2010	Reviewed - Medical Policy Group – Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group – Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2009	Annual policy review. No changes to policy statements.
6/2009	Annual policy review. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group – Gastroenterology, Nutrition & Organ Transplants, No changes to policy statements.
5/2008	Annual policy review. Policy guidelines updated. No changes to policy statements.
11/2007	Reviewed - Medical Policy Group – Gastroenterology, Nutrition and Organ Transplants. No changes to policy statements.
11/2006	Reviewed - Medical Policy Group – Gastroenterology, Nutrition and Organ Transplants. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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