MEDICAL POLICY

POLICY TITLE	LUNG AND LOBAR LUNG TRANSPLANT
POLICY NUMBER	MP 9.015

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**12/1/2024**

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I. POLICY

Lung transplantation may be considered **medically necessary** for carefully selected individuals with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy (see Policy Guidelines)

A lobar lung transplant from a living or deceased donor may be considered **medically necessary** for carefully selected individuals with end-stage pulmonary disease (see Policy Guidelines).

Lung or lobar lung retransplantation after a failed lung or lobar lung transplant may be considered **medically necessary** in individuals who meet criteria for lung transplantation.

Lung or lobar lung transplantation is considered **investigational** in all other situations, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

Contraindications

Potential contraindications subject to the judgment of the transplant center:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to lung disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Policy specific:

- Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function*; or
- Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

*Some individuals may be candidates for combined heart-lung transplantation (see MP 9.014).

Individuals must meet United Network for Organ Sharing (UNOS) guidelines for Lung Allocation Score (LAS) greater than zero.

Lung Specific Guidelines

Bilateral lung transplantation is typically required when chronic lung infection disease is present, i.e., associated with cystic fibrosis and bronchiectasis. Some, but not all, cases of pulmonary hypertension will require bilateral lung transplantation.

Bronchiolitis obliterans is associated with chronic lung transplant rejection, and thus may be the etiology of a request for lung retransplantation.

Cross-references:

MP 8.008 Outpatient Pulmonary Rehabilitation
MP 9.014 Heart/Lung Transplant

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. 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 Organ Procurement and Transplantation Network and United Network of Organ Sharing.

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LUNG TRANSPLANT

In 2022, 42,880 transplants were performed in the United States procured from 14,900 deceased donors and 6,400 living donors. 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 (COPD), idiopathic pulmonary fibrosis, cystic fibrosis, α_1-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. 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 post-transplantation, respectively. Skin cancer occurred most frequently, and lymphoproliferative disorders were the malignancies most associated with morbidity post-transplantation.

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. 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. 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. 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*).

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. 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.

REGULATORY STATUS

Solid organ transplants are a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Solid organs used for transplants are subject to these regulations.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have end-stage pulmonary disease who receive lung transplantation, the evidence includes case series and registry studies. Relevant outcomes are overall survival, 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 patients 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 a meaningful improvement in the net health outcome.

For individuals who have end-stage pulmonary disease who receive lobar lung transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, 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 the available published studies ranging from 50% to 100%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a prior lung or lobar transplant who meet criteria for a lung transplant who receive a lung or lobar lung retransplant, the evidence includes case series and registry studies. Relevant outcomes are overall survival, change in disease status, 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 without retransplantation of patients who have exhausted other treatments, evidence of a moderate level of posttransplant survival is sufficient in this patient population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

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CADAVER refers to a dead body or corpse.

END-STAGE refers to the final phase of a disease process.

LOBE is a well-defined part of an organ separated by boundaries, especially glandular organs and the brain.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
S2060	S2061	32850	32851	32852	32853	32854	32855
32856							

ICD-10-CM Diagnosis Codes	Description
C96.6	Unifocal Langerhans-cell histiocytosis
D86.0	Sarcoidosis of lung
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
E84.0	Cystic fibrosis with pulmonary manifestations
E84.8	Cystic fibrosis with other manifestations

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ICD-10-CM Diagnosis Codes	Description
E88.01	Alpha-1-antitrypsin deficiency
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale
I26.03	Cement embolism of pulmonary artery with acute cor pulmonale
I26.04	Fat embolism of pulmonary artery with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale
I26.93	Single subsegmental thrombotic pulmonary embolism without acute cor pulmonale
I26.94	Multiple subsegmental thrombotic pulmonary emboli without acute cor pulmonale
I26.95	Cement embolism of pulmonary artery without acute cor pulmonale
I26.96	Fat embolism of pulmonary artery without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.0	Primary pulmonary hypertension
I27.2	Other secondary pulmonary hypertension (includes pulmonary hypertension due to cardiac disease)
I27.21	Secondary pulmonary arterial hypertension
I27.22	Pulmonary hypertension due to left heart disease
I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I27.24	Chronic thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension
I27.82	Chronic pulmonary embolism
I27.83	Eisenmenger's syndrome
I27.89	Other specified pulmonary heart diseases (includes Eisenmenger's syndrome)
J42	Unspecified chronic bronchitis
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J84.10	Pulmonary fibrosis, unspecified

ICD-10-CM Diagnosis Codes	Description
J84.112	Idiopathic pulmonary fibrosis
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
J84.81	Lymphangioleiomyomatosis
J98.2	Interstitial emphysema
J98.3	Compensatory emphysema
M34.81	Systemic sclerosis with lung involvement
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
Q33.4	Congenital bronchiectasis
Z86.711	Personal history of pulmonary embolism

IX. REFERENCES

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X. POLICY HISTORY

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MP 9.015	**02/11/2020 Consensus Review**. References and coding reviewed. No changes to policy statements.
	09/01/2020 Administrative Update. Added ICD-10 J84.178
	05/03/2021 Consensus Review. No change to policy statement. References updated. Revised Description/Background section. Added diagnosis code I27.0 and J84.170. Removed J84.17.
	12/08/2022 Minor Review. Deleted the indications table from policy statement. Updated FEP, background, definitions, coding table, and references.
	08/29/2023 Consensus Review. No change to policy statement. Background updated. References reviewed and updated. No coding changes.
	08/16/2024 Administrative Update. Added new ICD-10 codes I26.03, I26.04, I26.95, and I26.96. Revised description of ICD-10 codes I26.93 and I26.94. Codes effective from 10/1/24.
	08/20/2024 No change to policy statements. References reviewed and updated. No coding changes.

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