MEDICAL POLICY

POLICY TITLE	LUNG AND LOBAR LUNG TRANSPLANT
POLICY NUMBER	MP-9.015

Original Issue Date (Created):	**7/10/2002**
Most Recent Review Date (Revised):	**2/11/2020**
Effective Date:	**10/1/2020**

I. POLICY

Lung transplantation may be considered **medically necessary** for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy, including, but not limited to one of the conditions listed in Table 1.

A lobar lung transplant from a living or deceased donor may be considered **medically necessary** for carefully selected patients with end-stage pulmonary disease including, but not limited to, one of the conditions listed in Table 1.

Table 1. Conditions

Conditions
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 syndrome

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, as there is insufficient evidence to support a 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 patients may be candidates for combined heart-lung transplantation (see MP-9.014).

Patients 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 BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

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FEP PPO - Refer to FEP Medical Policy Manual MP-7.03.07, Lung and Lobar Lung Transplant. 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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END-STAGE LUNG DISEASE

End-stage lung disease may be the consequence of a number of different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, α_1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension.

Treatment

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.

Since 2005, potential recipients have been ranked according to the Lung Allocation Score.[1] Patients 12 years of age and older receive a score between 1 and 100 based on predicted survival after transplantation reduced by predicted survival on the waiting list; the Lung Allocation Score takes into consideration the patient's disease and clinical parameters. In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 years 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.

REGULATORY STATUS

Lung transplantation is 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. Pancreas transplants are included in 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.

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V. DEFINITIONS TOP

BLUE DISTINCTION CENTERS FOR TRANSPLANT (BDCT) is a cooperative effort of the Blue Cross and Blue Shield Plans, the Blue Cross and Blue Shield Association and participating medical institutions to provide patients who need transplants, with access to leading centers through a coordinated, streamlined program of transplant management.

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 TOP

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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER TOP

Capital BlueCross's 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 BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

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:

CPT Codes ®							
32850	32851	32852	32853	32854	32855	32856	

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HCPCS Codes	Description
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor

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
E88.01	Alpha-1-antitrypsin deficiency
I26.01	Pulmonary embolism with acute cor pulmonale
I26.02	Saddle embolus 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 pulmonary embolism without acute cor pulmonale
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
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

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ICD-10-CM Diagnosis Codes	Description
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
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
J84.112	Idiopathic pulmonary fibrosis
J84.17	Other interstitial pulmonary diseases with fibrosis 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

TOP

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Other:

Taber's Cyclopedic Medical Dictionary, 20th edition.

X. POLICY HISTORY

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MP 9.015	**CAC 7/29/03**
	CAC 4/26/05
	CAC 4/25/06
	CAC 4/24/07 Consensus
	CAC 5/27/08 Consensus
	CAC 5/26/09 Consensus
	CAC 5/25/10 Consensus
	CAC 4/26/11 Adopted BCBSA. Some transplant indications were removed, however a qualifying statement of "including but not limited to the following indications" was also added. A "medically necessary" statement was added for lobar lung transplant for children and adolescents with end-stage pulmonary disease. A "not medically necessary" statement was added for patients with absolute contraindications.
	CAC 6/26/12 Consensus review. No changes, references updated. FEP variation added.
	04/08/13 Codes added to policy
	CAC 7/30/13 Consensus. In lobar lung statement, "children and adolescents" replaced with "carefully selected patients". No change to intent of policy meaning. Policy guidelines section added – the information was previously included in Background/Description.

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	CAC 3/25/14 Minor revision. Policy statement added indicating lung or lobar lung retransplantation may be medically necessary after a failed lung or lobar lung transplant. Policy statement added that lung or lobar lung transplantation is considered investigational in all other situations. References updated. Rationale added.
	CAC 3/24/15 Consensus. No change to policy statements. References and rationale updated. Codes reviewed.
	CAC 3/29/16 Consensus. No change to policy statements. References and rationale reviewed. Coding reviewed**.**
	Admin update 1/1/17: Product variation section reformatted.
	CAC 3/28/17 Consensus. Policy statements unchanged. Reference and Rationale sections updated. Coding reviewed.
	10/1/17 Administrative update Added new ICD-10 codes effective from 10/1/17 and deleted old ICD-10 codes.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
	1/16/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	1/24/19 Consensus review. Policy statements unchanged. Background and references updated. Rationale condensed. **4/3/19** Code review completed. No changes.
	10/1/19 Coding update. New ICD10 codes added to policy, effective 10/01/2019.
	02/11/2020 Consensus review. References and coding reviewed. No changes to policy statements.
	9/1/20 Administrative update. Added ICD 10 J84.178

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