

MEDICAL POLICY – 7.03.07

Lung and Lobar Lung Transplant

BCBSA Ref. Policy: 7.03.07

Effective Date: Nov. 1, 2024

Last Revised: Oct. 7, 2024


Replaces: Extracted from
7.03.509

RELATED MEDICAL POLICIES:

7.03.08 Heart/Lung Transplant

Select a hyperlink below to be directed to that section.

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Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a lung or a lobar lung may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Transplant	Medical Necessity
Lung transplant	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 Related Information below).
Lobar lung transplant	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 Related Information below).
Lung or lobar lung retransplantation	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.

Transplant	Investigational
Lung or lobar lung transplant	Lung or lobar lung transplantation is considered investigational in all other situations not outlined above.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical documenting the individual has irreversible, progressively disabling, end-stage pulmonary disease that has been unresponsive to maximum medical therapy. Please note the medical therapy trialed and failed. Please specify if request is for lung, lobar lung or retransplantation.

Coding



Code	Description
CPT	
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	
S2060	Lobar lung transplantation
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 of pre and posttransplant care in the global definition

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Related Information

Lung-Specific Guidelines

Bilateral lung transplantation is typically required when chronic lung infection and 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.



Contraindications

The factors below are 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 diseases 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^a; or
- Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

Note: ^a Some individuals may be candidates for combined heart and lung transplantation (see [Related Policies](#)).

Individuals must meet United Network for Organ Sharing guidelines for a Lung Allocation Score greater than zero.

Benefit Application

See individual's plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.



Description

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

Background

Solid organ transplantation offers a treatment option for individuals with different types of end stage organ failure that can be lifesaving or provide significant improvements to an individual'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. Individuals 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 2023, 46,630 transplants were performed in the US procured from more than 16,000 deceased donors and 6,900 living donors.² Lung transplants were the fourth most common procedure with 3,026 transplants performed from both deceased and living donors in 2023.

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, α 1-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. Before consideration for transplant, individuals 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 individuals 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 one 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 one lobe obtained from each of two 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 individual'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 individuals reporting one or more malignancies at five 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 individuals with HIV disease.⁷ These criteria for adding an individual 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 individuals (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 individuals (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 individuals infected with nonepidemic *B. cenocepacia* or *B. gladioli* were lower. In a smaller study



of 22 individuals colonized with *Burkholderia cepacia* complex who underwent lung transplantation in two French centers, Boussaud et al (2008) reported that the risk of death by univariate analysis was significantly higher for the eight individuals infected with *B. cenocepacia* than for the other 14 colonized individuals (11 of whom had *B. multivorans*).¹⁰

An analysis of international registry data by Yusef 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 three (0.1%) of the deaths were due to CMV infection.

Summary of Evidence

For individuals who have end-stage pulmonary disease who receive a lung transplant, the evidence includes case series and registry studies. The relevant outcomes are overall survival (OS), change in disease status, and treatment-related mortality and morbidity. International registry data on a large number of individuals receiving lung transplantation (>50,000) found relatively high individual 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 individuals 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. The 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 individuals unable to wait for a whole-lung transplant. A 2017 systematic review found one 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. The relevant outcomes are OS, change in disease status, treatment-related mortality and



morbidity. Data from registries and case series have found favorable outcomes with lung retransplantation in individuals who meet criteria for initial lung transplantation. Given the exceedingly poor survival prognosis without retransplantation of individuals who have exhausted other treatments, the evidence of a moderate level of posttransplant survival may be considered sufficient in this individual population. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT00177918	Prospective Evaluations of Infectious Complication in Lung Transplant Recipients	600	Dec 2025
Unpublished			
NCT00905463	Analysis of Prognosis and Patients Reported Outcomes in Lung Transplant Candidates	272 (actual)	Mar 2022 (last update 2019)

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence. Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.



International Society for Heart and Lung Transplantation

Initial Transplant

In 2021, the International Society for Heart and Lung Transplantation published updated consensus-based guidelines on the selection of lung transplant candidates.²⁹ The guidelines state that:

- "Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:
 1. High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.
 2. High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function."

The guideline also notes risk factors to be considered in the evaluation of transplant candidates, along with pediatric and disease-specific considerations.

Retransplant

The 2021 guideline update briefly addressed lung retransplantation, with the consensus statement noting that "The outcomes after re-transplants are inferior compared to first lung transplants, particularly if the re-transplant is done within the first year after the original transplant or for patients with restrictive allograft syndrome (RAS) [...] In the pre-transplant evaluation of such patients, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence, gastroesophageal reflux, or repeated infections".²⁹

American Thoracic Society et al

Evidence-based recommendations from the American Thoracic Society and three international cardiac societies were published in 2011 for the diagnosis and management of individuals with



idiopathic fibrosis.³⁰ For appropriately selected individuals with idiopathic pulmonary fibrosis, the international guideline panel recommended lung transplantation (strong recommendation, low-quality evidence). An update to this document was published in 2015 in which the committee did not make a recommendation regarding single versus bilateral lung transplantation in individuals with idiopathic fibrosis.³¹ The committee stated that "it is unclear whether single or bilateral lung transplantation is preferential for long-term outcomes".

In 2022, the American Thoracic Society along with the three other international cardiac societies published updated guidance on diagnosis and management of idiopathic pulmonary fibrosis and progressive pulmonary fibrosis.³² In terms of treatment considerations, the committee stated that "patients at increased risk of mortality should be referred for lung transplantation at diagnosis".

In 2014, the American Thoracic Society published guidelines on the management of bronchiolitis obliterans syndrome in lung transplant recipients in conjunction with the International Society for Heart and Lung Transplantation and the European Respiratory Society.³³ The guideline recommends referral to a transplant surgeon to be evaluated for retransplantation for end-stage bronchial obliterans syndrome that is refractory to other therapies.

Medicare National Coverage

Lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria³⁴ The Centers for Medicare & Medicaid Services have stated that, under certain limited cases, exceptions to the facility-related criteria may be warranted if there is justification and the facility ensures safety and efficacy objectives.

Regulatory Status

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the US Food and Drug Administration (FDA).

The FDA 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 for transplantation are subject to these regulations.

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History

Date	Comments
11/01/19	New policy, approved October 4, 2019. Content previously addressed in policy 7.03.509. Policy created with literature review through June 2019. Lung and lobar lung transplantation may be considered medically necessary when criteria are met. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14.
12/01/20	Annual Review, approved November 3, 2020. Policy updated with literature review through June 2020; references added. Policy statements unchanged.
06/01/21	Update Related Policies. Removed Policy 8.03.05 as it has been archived.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through June 29, 2021; no references added. Policy statements unchanged.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 23, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Annual Review, approved October 9, 2023. Policy updated with literature review through June 21, 2023; references added. Removed the policy statement regarding the transplantation of HCV-viremic solid organs to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 18, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

