

## Corporate Medical Policy

### Lung and Lobar Lung Transplantation

<b>File Name:</b>	lung_and_lobar_lung_transplantation
<b>Origination:</b>	3/1997
<b>Last CAP Review:</b>	3/2020
<b>Next CAP Review:</b>	3/2021
<b>Last Review:</b>	3/2020

#### **Description of Procedure or Service**

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

##### **Background**

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 (COPD), idiopathic pulmonary fibrosis (IPF), cystic fibrosis (CF), alpha-1 antitrypsin deficiency, and idiopathic pulmonary arterial hypertension (IPAH). Prior to the consideration for transplant, patients should be receiving maximal medical therapy such as oxygen supplementation or surgical options such as lung-volume reduction surgery for COPD. 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 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 (e.g., mother and father) in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants. Combined lung-pancreatic islet cell transplant is being studied for patients with cystic fibrosis.

Since 2005, potential recipients have been ranked according to the Lung Allocation Score (LAS). 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 LAS takes into consideration the patient's disease and clinical parameters. In 2010, a simple priority system was implemented for children under the age of 12. Under this system, children under 12 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 (LRB) has authority to adjust scores on appeal for adults and children.

##### **Related Policies:**

Heart/Lung Transplant

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### **Policy**

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# Lung and Lobar Lung Transplantation

**BCBSNC will provide coverage for Lung and Lobar Lung Transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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**Please refer to certificate for availability of benefit.** Certificates may specifically exclude transplantation procedures from coverage. Certificate language should verify application of medical necessity in making benefit determinations. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

- Coverage for medically necessary lung transplant procedures will be determined based on the member's certificate, the medical criteria and guidelines for coverage, and review on an individual basis.
- The benefit begins at the time of admission for the transplant, or once the patient is determined eligible for the transplant, which may include tests or office visits prior to the actual transplant.
- The benefit ends at the time of discharge from the hospital, or at the end of the required follow-up, including the immunosuppressive drugs administered on an outpatient basis.
- Expenses incurred in the evaluation and procurement of organs and tissues are a covered benefit when billed by the hospital. Included in these expenses may be specific charges for participation with registries for organ procurement, operating rooms, supplies, use of hospital equipment, and transportation of the tissue or organ to be evaluated.
- Coverage is not provided for organs sold rather than donated to the recipient.

## When Lung and Lobar Lung Transplantation is covered

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- A.) Lung or lobar 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 below.
- B.) 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 below.
  - 1) Patients with debilitating lung disease (functional status of the New York Heart Association Class III after maximal rehabilitation). Examples include:
    - a) Cystic fibrosis (both lungs to be transplanted)
    - b) Primary pulmonary hypertension
    - c) Chronic obstructive pulmonary disease- the FEV1 post bronchodilator less than 25% predicted
    - d) Bilateral bronchiectasis
    - e) Alpha-1 antitrypsin deficiency
    - f) Bronchopulmonary dysplasia
    - g) Idiopathic/interstitial pulmonary fibrosis
    - h) Postinflammatory pulmonary fibrosis
    - i) Sarcoidosis
    - j) Scleroderma

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- k) Lymphangiomyomatosis
  - l) Eosinophilic granuloma
  - m) Bronchiolitis obliterans
  - n) Recurrent pulmonary embolism
  - o) Pulmonary hypertension due to cardiac disease
  - p) Eisenmenger's syndrome
  - q) Emphysema
- C.) The patient is willing and capable of complying with the post transplant treatment plan.
- D.) The patient has adequate cardiac status.
- E.) HIV/AIDS is not necessarily an absolute contraindication to lung or lobar lung transplantation, but will be evaluated on an individual basis. See Policy Guidelines.
- F.) 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.

## **When Lung and Lobar Lung Transplantation is not covered**

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Lung and lobar transplantation is considered not medically necessary when the medical criteria listed above are not met.

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

## **Policy Guidelines**

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Approval for lung transplantation will be reviewed on an individual basis for medical necessity when the policy holder's certificate provides coverage for transplantation.

The literature on lung and lobar lung transplantation, which consists of, case series and registry data, demonstrates that lung transplantation provides a survival benefit in appropriately selected patients and thus may be considered medically necessary. It may be the only option for some patients with end-stage lung disease.

The literature on lung retransplantation is limited but is accumulating in registry data. As in lung transplantation, lung retransplantation may be the only option for patients with failed lung transplantation.

Potential contraindications subject to the judgement of the transplant center:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
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 dependency affecting ability to adhere to therapy
8. Current smoking

### **Policy-specific**

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Coronary artery disease (CAD) 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.

Patients must meet UNOS guidelines for lung allocation score (LAS) greater than zero.

## **Lung Specific**

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.

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.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable Codes: 32850, 32851, 32852, 32853, 32854, 32855, 32856, S2060, S2061*

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual - 12/95

NIH selection criteria for lung transplantation, by Handelsman, 1991, Exclusionary criteria published in the Federal Register, Volume 60, Number 22, Feb. 2, 1995

UNOS (United Network for Organ Sharing) Criteria, published 8/13/96. The generally accepted maximal age limits are 65 for SLT, 60 years for Bilateral Single Lung, and 55 for HL Txp.

Maurer JR, Frost AE, Estenne M, Higenbottam T, Glanville AR. Lung and Heart-Lung Transplantation. International Guidelines for the Selection of Lung Transplant candidates. The Journal of Heart and Lung Transplantation 1998; (Volume 17, No. 7)703-709

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Specialty Matched Consultant Advisory Panel - 5/2001

BCBSA Medical Policy Reference Manual - 12/18/02, 7.03.07.

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Wood DE, Raghu G. (December 1996). Lung Transplantation Part 1. Indications and Operative Management. West J Med 1996; 165: 355-363

Glanville AR, Estenne M. (April 2003). Indications, patient selection and timing of referral for lung transplantation. Eur Respir J 2003; 22: 845-852

Nathan SD. (March 2005). Lung Transplantation: Disease-Specific Considerations for Referral. Chest 2005; 127: 1006-1016

National Institute for Clinical Excellence (NICE). Guidance on Living-donor lung transplantation for end-stage lung disease. Interventional Procedure Guidance 170. London, UK: NICE; May 2006. Retrieved 4/2/ 07 from <http://guidance.nice.org.uk/download.aspx?o=IPG170guidance>

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Yusen RD, Shearon TH, Qian Y et al. Lung transplantation in the United States, 1999-2008. Am J Transplant 2010; 10(4 Pt 2):1047-68.

Specialty Matched Consultant Advisory Panel review 3-2011

United Network for Organ Sharing (UNOS). Questions and answers for professionals about lung allocation policy. Available online at <http://www.unos.org/docs/Lung> Professional. pdf. Last accessed November 2011.

# Lung and Lobar Lung Transplantation

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 2/14/13

Specialty Matched Consultant Advisory Panel review 3/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 1/9/14

Specialty Matched Consultant Advisory Panel review 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 1/15/15

Specialty Matched Consultant Advisory Panel review 3/2015

Specialty Matched Consultant Advisory Panel review 3/2016

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 8/10/17

Specialty Matched Consultant Advisory Panel review 3/2018

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# Lung and Lobar Lung Transplantation

Specialty Matched Consultant Advisory Panel review 3/2020

## **Policy Implementation/Update Information**

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8/88 Reviewed: Investigational  
7/91 Evaluated: Eligible for coverage  
12/95 Reaffirmed by Association. Specific diagnoses added.

### **Local Review Dates:**

1/93 Reviewed: PCP Physician Advisory Group  
11/94 Reviewed: PCP Physician Advisory Group  
11/95 Reviewed: PCP Physician Advisory Group  
3/96 Reviewed: Accepted Association's revised policy.  
3/97 Reaffirmed  
3/99 Reaffirmed  
9/99 Reformatted, Description of Procedure or Service revised, Medical Term Definitions added.  
12/99 Medical Policy Advisory Group  
3/01 System change.  
8/01 Specialty Matched Consultant Advisory Panel meeting 5/2001. Policy revised to include recommendations for when services are and are not covered. Added approval indications for lobar lung transplant.  
5/03 Specialty Matched Consultant Advisory Panel meeting 5/2003. No change to policy. Format change. Reaffirm.  
4/04 Code S2152 added to Billing/Coding section of policy.  
8/12/04 Paragraph added to Procedure Description section to include lobar lung transplants (3rd paragraph). Last statement in Procedure Description section changed to begin, "These transplants are intended..." to include lobar lung transplants. Typo corrected (HIV positive). Codes S2060 and S2061 added to Billing and Coding section. References added.  
8/26/04 Title changed from "Single and Double Lung Transplantation" to "Lung and Lobar Lung Transplantation." All code descriptions removed. "Lobar Transplantation" added as a key word.  
9/09/04 Formatting changes.  
1/6/05 Codes 32855, 32856 added to Billing/Coding section of policy.  
7/07/05 Specialty Matched Consultant Advisory Panel review on 05/26/2005. No changes made to policy statement. Added SUR6650 to keywords. Reference added. Changed 1.n under Covered Section to eliminate (Eisenmenger's syndrome), added Eisenmenger's syndrome for 1.o, and chronic obstructive pulmonary disease for 1.p. Four bullet points added to Benefits Application section for consistency with other transplant policies as well as member booklet information.  
7/2/07 Deleted code S2152. References updated. Specialty Matched Consultant Advisory Panel review meeting 5/25/07. No changes to policy coverage criteria. (adn)

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- 5/19/08 From the When Covered section, deleted redundant phrase, "pulmonary fibrosis" and age limitation, and added the phrase, "The patient has adequate cardiac status." Also added the following phrase to the When Covered section, "HIV/AIDS is not necessarily an absolute contraindication to lung or lobar lung transplantation, but will be evaluated on an individual consideration basis. See Policy Guidelines." In the When Not Covered section: Item 2. Contraindications related to infections--deleted items a) HIV positive, with or without AIDS; b) Hepatitis D positive blood test; c) Active TB infection; d) Pan-resistant Burkholderia cepacia in patients with cystic fibrosis, and e) Bacterial sepsis. Replaced statements in Item 2 with: a) Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B or C; and b) Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria is a relative contraindication to be included in a comprehensive evaluation of all other comorbidities. Added the following statement to Contraindications related to other diseases, Item 3. e. iii. "Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or association with significant impairment of left ventricular function (however, heart-lung transplantation could be considered in highly selected cases)." Deleted Item 8. Ventricular heart failure. The following statement was added to the Policy Guidelines section: "In patients with cystic fibrosis there are no absolute contraindications based on either the type of the organism or the pattern of resistance. For all patients, including those with end-stage lung disease and HIV infection, evaluation of a candidate for transplant needs to consider the probability of a successful transplant and the limited supply of organs available. Some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease. Furthermore, UNOS states that asymptomatic HIV+ patients should not necessarily be excluded for candidacy for organ transplantation, stating "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy." In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant unless the following criteria were present: CD4 count >200 cells/mm<sup>3</sup> for greater than 6 months, HIV-1 RNA undetectable, On stable anti-retroviral therapy for greater than 3 months, No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm), Meeting all other criteria for transplantation. Questions and concerns have been raised about the extrapolation of these criteria to lung and lobar lung transplant. (adn)
- 6/22/09 When Covered section reformatted. Added the word "interstitial" to Item B.1.a. in the When Covered section. Specialty Matched Consultant Advisory Panel review meeting 5/13/09. No change to policy statement.
- 6/22/10 Policy Number(s) removed (amw)
- 4/12/11 Specialty Matched Consultant Advisory Panel review 3-2011. References updated. Revised statement in "When not Covered" section from "Current cancer in any part of the body" to "Known current malignancy, including metastatic cancer." Policy Guidelines updated. Added the following statement to the "Benefits Application" section: "Coverage is not provided for organs sold rather than donated to the recipient."(mco)
- 3/30/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. Revised description section extensively as well as Policy Guidelines and When Not Covered sections. Reordered covered indications under When Covered section. Added references. No change to policy statement. (lpr)



## Lung and Lobar Lung Transplantation

- 4/16/13 Under “When Covered” section added statement: 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 below-also added emphysema as a condition under this list. Specialty Matched Consultant Advisory panel review meeting 3/20/2013. Reference added. No change to policy statement. (lpr)
- 2/25/14 Under “When Covered” section: added the statement “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.” Under “When Not Covered” section: added the statement “Lung or lobar lung transplantation is considered investigational in all other situations.” References updated. (lpr)
- 5/13/14 Specialty matched consultant advisory panel review meeting 4/30/2014. No change to policy statement. (lpr)
- 2/24/15 Reference added. (lpr)
- 4/28/15 Specialty matched consultant advisory panel review 3/25/2015. No change to policy statement. (lpr)
- 4/29/16 Specialty Matched Consultant Advisory Panel review 3/30/2016. Added current smoking as a potential contraindication under Policy Guidelines. No change to policy statement. (lpr)
- 4/28/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. No change to policy statement. (lpr)
- 9/29/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)
- 9/7/18 Reference added. (lpr)
- 4/30/19 Specialty Matched Consultant Advisory Panel review 3/20/19. No change to policy statement. (lpr)
- 4/28/20 References added. Specialty Matched Consultant Advisory Panel review 3/31/2020. No change to policy statement. (eel)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.