

## Corporate Medical Policy

# Lung and Lobar Lung Transplant

**File Name:** lung\_and\_lobar\_lung\_transplantation  
**Origination:** 3/1997  
**Last Review:** 5/2009  
**Next Review:** 5/2011

### Description of Procedure or Service

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Single lung transplantation begins with a thoracotomy, which is a surgical procedure where an incision is made to open the chest cavity. After removal of the native lung, the major vessels are anastomosed (connected) to the donor lung and then to the bronchi. The bronchi are the larger air passages of the lungs.

There are two main techniques for double lung transplantation. The earlier method involved a median sternotomy and removing the lungs as a whole and then connecting them at the trachea. The trachea is also known as the windpipe and is a tube of cartilage lined with mucous membrane passing from the larynx to the bronchi of the lungs. The more recent method uses a transverse (diagonal) thoracotomy with separate transplantation of each lung with bilateral airway anastomoses or connections to the donor lung at the bronchi.

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 transplants have been primarily living-related donors, with one lobe obtained from each of two donors (e.g., mother and father) in cases where a bilateral transplant is required. There are also cases of cadaver lobe transplants.

These lung transplantations are intended to prolong survival and improve function in patients with severe pulmonary disease.

### Policy

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**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 consideration 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,

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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.

### When Lung and Lobar Lung Transplantation is covered

- A. Lung or lobar lung transplantation may be considered medically necessary for carefully selected patients with irreversible, progressively disabling, 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. Idiopathic/Interstitial pulmonary fibrosis - with significant impairment of FVC (e.g. FVC less than 65% of predicted);
    - b. Cystic fibrosis (both lungs to be transplanted) - with severe impairment of FVC (e.g. less than 40% of predicted), FEV1 (e.g. less than 30% of predicted), and room air PaO<sub>2</sub> (e.g. less than 60 mmHg);
    - c. Primary pulmonary hypertension
    - d. Emphysema - the FEV1 post bronchodilator less than 25% predicted
    - e. Bilateral bronchiectasis
    - f. Alpha-1 antitrypsin deficiency
    - g. Bronchopulmonary dysplasia
    - h. Interstitial pulmonary fibrosis
    - i. Sarcoidosis
    - j. Scleroderma
    - k. Lymphangiomyomatosis
    - l. Eosinophilic granuloma
    - m. Bronchiolitis obliterans
    - n. Recurrent pulmonary embolism
    - o. Pulmonary hypertension due to cardiac disease
    - p. Eisenmenger's syndrome
    - q. Chronic Obstructive Pulmonary Disease
- B. The patient is willing and capable of complying with the post transplant treatment plan.
- C. The patient has adequate cardiac status.
- D. 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.

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

Lung transplantation is not covered when the patient has **any one** of the contraindications shown below:

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1. General contraindications
  - a. Active drug or alcohol abuse, or tobacco use within the last 6 months
  - b. Obesity (over 20-30% over ideal body weight) at time of transplant
  - c. Contraindication to immunosuppressive drugs
  - d. Multiple uncorrectable congenital abnormalities that significantly affect quality and duration of life (such as anencephaly or other severe congenital anomalies)
2. Contraindications related to infections
  - a. Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B or C
  - 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
3. Contraindications related to other diseases
  - a. Current cancer in any part of the body
  - b. Cancer that, based upon the type and duration of disease-free survival to date, has a significant likelihood of recurring
  - c. Bone marrow failure (any cell line)
  - d. Severe congenital immunodeficiency
  - e. Significant or advanced other disease including:
    - i. Hepatic dysfunction, including cirrhosis and chronic liver disease
    - ii. Renal dysfunction (creatinine over 1.5 or clearance less than 50 ml/min or less than 35 ml/min for pulmonary hypertension patients)
    - iii. Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function (however, heart-lung transplantation could be considered in highly selected cases)
  - f. Other systemic disease that impairs function or expected duration of life
  - g. Cerebral dysfunction, such as severe impairments which affect quality of life and ability to comply with transplant regimen
  - h. Behavioral or psychiatric disorder considered likely to compromise adherence with strict medical regimen and follow-up after transplant, including physical rehabilitation
4. Advanced physiologic age
5. Emotional problems or recent substance abuse (including smoking)
6. History of non-compliance with medical management
7. Lack of social support

## 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.

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

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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.

## 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.bcbsnc.com](http://www.bcbsnc.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.*

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

Medical Policy Advisory Group Review - 3/99

## Policy: Lung and Lobar Lung Transplant

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 5/2001

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

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 02/25/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 11/9/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 3/7/06

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>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 4/09/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.07, 4/24/09

### 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.

## Policy: Lung and Lobar Lung Transplant

- 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.
- 7/07/2005 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)
- 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)

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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)

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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.