

SUBJECT: LUNG AND LOBAR LUNG TRANSPLANT

POLICY NUMBER: 7.02.10

CATEGORY: Transplants

EFFECTIVE DATE: 04/20/00

REVISED DATE: 02/21/02, 02/20/03, 01/15/04, 01/20/05, 01/19/06, 02/15/07, 01/17/08, 03/19/09, 03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/20/14

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, lung transplantation has been medically proven to be effective and therefore **medically appropriate** for carefully selected candidates who have irreversible, progressively disabling end-stage pulmonary disease and meet all of the following criteria:

- Adequate cardiac status;
- Absence of infection, or extrapulmonary infection in patients with cystic fibrosis;
- No history of malignancy within 5 years of transplantation excluding nonmelanomatous skin cancers;
- Documentation of patient compliance with medical management.

Indications include, but are not limited to, the following:

- Bilateral bronchiectasis,
- Congenital bronchiectasis,
- Alpha-1 antitrypsin deficiency,
- Primary pulmonary hypertension,
- Cystic fibrosis,
- Bronchopulmonary dysplasia,
- Idiopathic pulmonary fibrosis,
- Interstitial pulmonary fibrosis,
- Sarcoidosis,
- Scleroderma,
- Lymphangiomatosis,
- Emphysema,
- Eosinophilic granuloma,
- Bronchiolitis obliterans,
- Recurrent pulmonary embolism,
- Chronic obstructive pulmonary disease,
- Tuberculous fibrosis of lung,
- Pneumoconiosis and other lung diseases due to external agents, or
- Eisenmenger's syndrome.

II. Recipient Selection Guidelines:

Each recipient considered for transplantation should have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

- The following general medical conditions are felt to impact on the long-term outcome of lung transplant recipients. Other medical conditions, when they have not resulted in organ damage, are generally acceptable in candidates for lung transplantation (e.g., systemic hypertension, diabetes mellitus, peptic ulcer disease) and

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should be optimally treated and well controlled. In the presence of any comorbid medical condition with the potential for end organ damage, a careful search should be made for evidence of organ dysfunction.

1. Current use of corticosteroids is not a contraindication to transplantation. However, all attempts to discontinue these drugs or at least reduce the dose to less than or equal to 20 mg per day of prednisolone or prednisone should be made.
2. Nutritional issues are important predictors of surgical outcome. Patients with an ideal body weight less than 70% or greater than 130% require either weight gain or weight loss to become eligible for transplant.
3. Substance abuse issues need to be addressed prior to lung transplantation candidates must have been free of substance addiction (e.g., alcohol, tobacco, narcotics) for at least 6 months. Appropriate preoperative biochemical monitoring is recommended in at-risk patients.
4. Psychosocial problems that are unable to be resolved and that have a high likelihood of impacting negatively on the patients outcome (e.g., poorly controlled major psychoaffective disorder, inability to comply with complex medication regimen) are a relative contraindication. A documented history of noncompliance with medical care or treatment plans, even in the absence of a documented psychiatric condition, is a relative contraindication.
5. Colonization with fungi or atypical mycobacteria is not an absolute contraindication to transplantation. Cases should be considered on an individual basis. Special care should be taken when a unilateral transplant is considered. When possible, preoperative attempts to eradicate colonization with antibiotic therapy are appropriate. Adequately treated M. tuberculosis is not a contraindication to lung transplantation.

B. Contraindications to lung transplantation:

1. Absolute contraindications include:
 - a. Infection with HIV unless ALL of the following criteria are met:
 - i. CD4 count greater than 200 cells/mm³,
 - ii. HIV-1RNA undetectable,
 - iii. On stable anti-retroviral therapy greater than 3 months,
 - iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm), and
 - v. Meets all other criteria for transplantation.
 - b. Presence of malignancy (other than non-melanoma skin cancers), or unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
 - c. Progressive neuromuscular disease.
2. Relative contraindications include:

Dysfunction of major organs, other than the lung, is a contraindication. Particularly renal dysfunction (e.g., creatinine clearance of 50 mg/ml/min) because of the impact of immunosuppressive drugs on renal function. Patients with significant untreatable coronary artery disease or left ventricular dysfunction warrant consideration for heart-lung transplant.

 - a. Hepatitis B antigen positivity.
 - b. Hepatitis C with biopsy-proven histologic evidence of liver disease.
 - c. Symptomatic osteoporosis. The potential risk to acceptable long-term outcomes should be assessed on a case-by-case basis. Both symptomatic and asymptomatic significant disease requires treatment that should be initiated prior to transplantation. Patients should be fully investigated and followed by appropriate objective measures (e.g., bone densitometry).
 - d. Severe musculoskeletal disease affecting the thorax (e.g., kyphoscoliosis).
 - e. Requirement for invasive ventilation. Patients receiving noninvasive ventilatory support who meet all other criteria are eligible for lung transplantation.

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III. Living Donor Selection Guidelines:

Each donor considered for transplantation should have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation.

Any person who gives consent to be a live organ donor and is related to the recipient should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation for the living donor organ.

POLICY GUIDELINES:

- I. Prior Authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.
- II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing should be included in the documentation:
 - A. Clinical Evaluation:
 1. Confirmation of diagnosis;
 2. Identification of comorbidities;
 3. Treatment of co-morbidities;
 4. Current assessment of co-morbidities;
 5. Consult notes (if applicable).
 - B. Psycho-Social Evaluation:
 1. Karnofsky performance score;
 2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).
 - C. Dental Evaluation.
 - D. Lab Tests:
 1. CBC, metabolic profile;
 2. Serologies: CMV,
 3. Hepatitis B and C;
 4. HIV Testing.
 - E. Cardiac Assessment:
 1. 12 Lead EKG;
 2. Stress echo or MUGA Scan.
 - F. Pulmonary Assessment:
 1. Chest x-ray;
 2. Pulmonary function tests (PFTs).
 3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).
 - G. Age Appropriate Screening Tests:
 1. Age greater than or equal to 50 years:
 - a. Colonoscopy (within 10 years); or
 - b. Flexible sigmoidoscopy (within 5 years); or
 - c. Guaiac stool testing (within 1 year); or
 - d. Rationale of contraindication to testing (if applicable).
 2. Women age 21-70 years:

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- a. Pap smear (within 3 years).
- 3. Women age greater than or equal to 40 years:
 - a. Mammogram (within 2 years).

DESCRIPTION:

Lung transplantation offers carefully selected patients the only curative treatment for end-stage pulmonary parenchymal and vascular diseases.

A lung transplant, either single or double, involves the surgical removal of a lung from a cadaveric or living donor(s) into a recipient.

In an attempt to ease the shortage of available lungs for transplantation, especially lungs small enough to be suitable for children and adolescents, lobar transplants have been done. In a lobar transplant, a lobe of the donor's lung is excised, sized appropriately for the recipient's thoracic dimensions and is transplanted. Although donors for lobar transplant have primarily been living related donors there have been cases of cadaveric lobe transplants. In cases where a bilateral lobar transplant is required one lobe is obtained from each of two donors.

In 2005, UNOS began to use a new lung allocation system for patients 12 years of age and older based on wait list urgency and probability of prolonged survival following transplant. The system assigns a score using a candidate's diagnosis, New York Heart Association Class, use of a ventilator, diabetes treatment if applicable, oxygen required at rest, and pulmonary function and laboratory values. Waiting time is used only to sort candidates who have tie scores. Waiting time is a main factor, however, in allocating lungs for children under 12 years old. Other factors for pediatric candidates are ABO compatibility and distance from donor hospital. Transplant centers may update values at any time to reflect a change in disease severity.

The lung allocation system calculator is found at: www.unos.org/docs/lung_allocation_score.pdf.

RATIONALE:

Lung or lobar/lung transplantation represent the only curative approach for many carefully screened patients with end-stage pulmonary disease.

Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long term survival.

Solid organ transplantation for candidates that are HIV positive has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV+ transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, 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 specific criteria were present. These criteria are listed in this policy regarding HIV status and lung and lobar transplants.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	32851 Lung transplant, single; without cardiopulmonary bypass 32852 with cardiopulmonary bypass 32853 Lung transplant, double (bilateral, sequential, or en bloc); without cardiopulmonary bypass 32854 with cardiopulmonary bypass 32855 Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral 32856 bilateral
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HCPCS: No code(s)

<u>ICD9:</u>	135 Sarcoidosis 235.7 Lymphangiomyomatosis 277.00-277.09 Cystic fibrosis (code range) 277.6 Alpha-1 antitrypsin deficiency 277.81-277.89 Eosinophilic granuloma (code range) 415.11-415.19 Pulmonary embolism and infarction (code range) 416.0-416.9 Primary pulmonary hypertension (code range) 491.8 Bronchiolitis obliterans 492.0-492.8 Emphysema (code range) 494.0-494.1 Bronchiectasis (code range) 496 Chronic obstructive pulmonary disease 515 Interstitial pulmonary fibrosis 516.30-516.37 Idiopathic pulmonary fibrosis (code range) 517.8 Sarcoidosis 710.1 Scleroderma 745.4 Eisenmenger's defect or complex 748.61 Congenital bronchiectasis 770.7 Bronchopulmonary dysplasia
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<u>ICD10:</u>	
D38.1	Neoplasm of uncertain behavior of trachea, bronchus and lung
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
D86.0-D86.9	Sarcoidosis (code range)
E71.41	Primary carnitine deficiency
E84.0-E84.9	Cystic fibrosis (code range)
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.00-I27.9	Other pulmonary heart diseases (code range)
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0-J43.9	Other specified pulmonary heart diseases (code range)
J44.9	Chronic obstructive pulmonary disease, unspecified
J47.9	Bronchiectasis, uncomplicated
J84.10-J84.114	Other interstitial pulmonary diseases with fibrosis (code range)
J84.2	Lymphoid interstitial pneumonia
J84.89	Other specified interstitial pulmonary diseases
J99	Respiratory disorders in diseases classified elsewhere
M32.13	Lung involvement in systemic lupus erythematosus
M33.01-M33.91	Dermatopolymyositis (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)
M35.02	Sicca syndrome with lung involvement
P27.0-P27.9	Chronic respiratory disease originating in the perinatal period (code range)
Q21.0	Ventricular septal defect
Q33.4	Congenital bronchiectasis
T80.0xxA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter
T81.718A	Complication of other artery following a procedure, not elsewhere classified, initial encounter
T81.72xA	Complication of vein following a procedure, not elsewhere classified, initial encounter
T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
T82.818A	Embolism of vascular prosthetic devices, implants and grafts, initial encounter

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REFERENCES:

Adler FR, et al. Lung transplantation for Cystic Fibrosis. *Proc Am Thorac Soc* 2009;6:619-633.

Ahmad U, et al. Outcomes for lung transplantation for lung cancer in the United Network for Organ Sharing Registry. *Ann Thorac Surg* 2012;94(3):935-940.

Beaty CA, et al. Pre-transplant malignancy: an analysis of outcomes after thoracic organ transplantation. *J Heart Lung Transplant* 2012 Dec 19 [Epub ahead of print].

Bertani A, et al. Successful lung transplantation in an HIV- and HBV-positive patient with cystic fibrosis. *Am J Transplant* 2009;9:2190-2196.

Bittle GJ, et al. The use of lung donors older than 55 years: a review of the United Network of Organ Sharing database. *J Heart Lung Transplant* 2013 Aug;32(8):760-8.

BlueCross BlueShield Association. Lung and lobar lung transplantation. Medical Policy Reference Manual Policy #7.03.07. 2013 Dec 13.

Christie JD., et al. The Registry of the International Society for Heart and Lung Transplantation: twenty-eighth official adult lung and heart-lung transplant report-2011. *J Heart Lung Transplant* 2011;30(10):1104-1122.

Copeland CA, et al. Impact of lung transplantation upon recipient quality of life: a serial, prospective, multi-center analysis through the first posttransplant year. *Chest* 2012 Sep 24 [Epub ahead of print].

Dilling DF, et al. Advances in lung transplantation: the year in review. *J Heart Lung Transplant* 2011;30:247–251.

Eberlein M, et al. The effect of lung size mismatch on complications and resource utilization after bilateral lung transplantation. *J Heart Lung Transplant* 2012 Feb 9 [Epub ahead of print].

Kilic A, et al. Lung transplantation in patients 70 years old or older; have outcomes changed after implementation of the lung allocation score? *J Thorac Cardiovasc Surg* 2012 Nov;11(5):1133-1138.

Shigemura N, et al. Lobar lung transplantation: a relevant surgical option in the current era of lung allocation score. *Ann Thorac Surg* 2013 Aug;96(2):451-6.

*Steinman TI, et al. The clinical practice committee of the American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplant* 2001;71(9):1189-204.

Thabut G, et al. Survival differences following lung transplantation among US transplant centers. *JAMA* 2010;304(1):53-60.

Thabut , et al. Survival after bilateral versus single-lung transplantation for idiopathic pulmonary fibrosis. *Ann Intern Med* 2009;151:767-774.

*United Network for Organ Sharing. Policies, organ distribution, a guide to calculating the Lung Allocation Score. 2005 [www.unos.org/docs/lung_allocation_score.pdf] accessed 1/7/14.

Warnecke G, et al. Lung re-transplantation: review. *Curr Opin Organ Transplant* 2012 Oct;17(5):485-489.

Weiss ES, et al. Impact of advanced age in lung transplantation: an analysis of united network for organ sharing data. *J Am Coll Surg* 2009;208:400-409.

Yusen RD, et al. The Registry of the International Society for Heart and Lung Transplantation: thirtieth adult lung and heart-lung transplant report--2013; focus theme: age. *J Heart Lung Transplant* 2013; 32(10):965-78.

* key article

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KEY WORDS:

Lobar Lung Transplant, Lung Transplant.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) for Lung Transplants. However a Lung Transplant NCD is to be added to the following website for Medicare Members regarding Solid Organ Transplantation:
http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part4.pdf.