Subject: ***Lung Transplant***

Number: ***200306-0002***

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Important note
Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the terms of your own benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website:
http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp

Overview

Patients with crippling lung disease, causing severe shortness of breath and limitation of activities, are sometimes candidates for lung transplant. The patient's lungs are removed, and donated lungs replace them. The donated lungs may come from a cadaver (such as a brain-dead person kept on artificial life-support), or, if no cadaver is available, then from a living donor, such as a relative who gives part of a lung (a lobe). Often it takes several living relatives, each giving part of their lung (one lobe from each), to obtain enough lung for one transplant patient. Rarely, for children or small adolescents, a lobe (rather than whole lungs) may be taken transplanted.

Policy and criteria

NOTE: These services require prior authorization by the Plan Medical Director.

When services are covered:

Patients should be listed for **lung transplantation** when their predicted survival is less than 2 years. We cover the following services for patients who have none of the exclusionary criteria. In general, we cover lung transplants in patients up to age 65 for single lung, and patients up to age 60 for double lung.

- Medically necessary cadaveric lung transplants
- Living related lobar lung transplants for children and adolescents

In general, lung transplants for patients with debilitating lung disease (functional status NHYA Class III after maximal rehabilitation) are covered. Examples include:

Idiopathic pulmonary fibrosis (IPF)

- FVC less than 60-70% of predicted or diffusing capacity less than 50-60% predicted
- Symptomatic including (rest or exercise O_2 desaturation), progressive disease with failure to improve or maintain lung function while being treated with steroids or other immunosuppressive drug therapy

Cystic fibrosis (CF)

- FEV_1 < 30% of predicted, or
- FEV_1 >30% and rapid progressive respiratory deterioration (increasing hospitalization, rapid fall in FEV1, massive hemoptysis, and increasing cachexia despite optimal management).

Primary pulmonary hypertension (PPH) with or without congenital heart disease: for severe progressive symptoms referable to the disease, with function at NYHA III or IV despite optimal medical management.

Nonbronchiectatic chronic obstructive lung disease including emphysema, chronic bronchitis, and bronchiolitis obliterans. COPD patients must meet the following criteria:

- FEV_1<25% of predicted post-bronchodilator or anticipated to be < 25% at the time of surgery, or
- $PaCO_2 \geq$ 55 mm Hg, or
- Elevated pulmonary artery pressures with progressive deterioration (such as cor pulmonale)

Please refer to the **Transplant Policy** for supportive information regarding covered and non-covered services.

Relative contraindications

The following circumstances may make lung transplantation more challenging, or in some cases, less likely to succeed long-term. Any one of these alone may not be a reason to decline the requested transplantation. However, several of these together may make transplantation not the best option:

- Age over 65 for single lung, or over age 60 for double lung. Age is associated with factors such as osteopenia, deconditioning, and other factors affecting the success of transplantation.
- Chronic ventilator dependence (as morbidity and post-op convalescence are increased); patients who are ambulatory despite being on a ventilator are more likely to be successful that those who are bed-ridden.
- Current use of corticosteroids (either a reduced amount or a dose less than 20mg/day of prednisolone or prednisone or less than 40 mg very other day) is acceptable for adults. Doses under 0.3mg/kg/day in children are not associated with increased adverse events post-transplant. Steroids cause osteopenia, decreased muscle strength, and other problems associated with transplantation.
- Significant chest wall deformity, which impairs ventilation and post-operative rehabilitation.
- For **single lung** transplant only: when chronic or recurrent infection in the lung will which remain, since this infection may transfer to the transplanted lung
- For **double lung** transplant only, because these procedures make lung transplant technically more difficult:
  - History of thoracotomy with lung resection
  - History of median sternotomy
  - History of thoracostomy tube with pleurodesis
- **Cardiovascular**:
  - Irreversible right ventricular dysfunction due to non-pulmonary causes
  - RVEF less than 20% (note, degree of reversibility with transplant is not easily predicted)
  - Left ventricular dysfunction
  - Significant coronary artery disease

- **Viral** diseases
    - Hepatitis C: RNA positive (should be evaluated in context of degree of chronic liver disease)
    - Cytomegalovirus (CMV) with current illness (history of CMV is less problematic)
    - Epstein-Barr Virus (EBV) with current illness (history of EBV is not problematic)
- Active bacterial, fungal **infection** (UNOS considers pan-resistant bacteria or aspergillus in sputum a relative contraindication). Atypical mycobacteria and fungal infections are not absolute contraindications.
- **Cancer** that has been "cured": the likelihood of recurrence is based upon both the type of cancer and the duration of disease-free survival at time of listing.
- **Systemic hypertension** requiring multi-drug therapy, assuming that control could be maintained amidst transplant medication regimen
- **Rheumatic** (connective tissue) disease which may affect the transplanted lung:
    - pediatric patients – this is an absolute contraindication
    - The ASTP/NIH Conference consideres the following controversial or unusual, but not absolutely contraindicated: sarcoidosis, lymphangioleiomyomatosis (LAM), diffuse pan-bronchiolitis, giant cell interstitial pneumonitis, Kartagener's syndrome, collagen vascular diseases, amyloid, pulmonary alveolar proteinosis, Langerhans' cell granulomatosis (eosinophilic granuloma, histiocytosis X), radiation fibrosis, pulmonary hypertension from thromboembolic disease not amenable to surgery, and ARDS.
- **Peripheral vascular disease** with increased potential for thrombosis.
- Symptomatic **osteoporosis**, because it may impair rehabilitation.
- **Poorly-controlled diabetes mellitus** because medications after transplantation may worsen diabetes control.
- Severe **musculoskeletal disease** affecting the thorax, such as kyphoscoliosis.
- Psychosocial problems that are not resolved, poorly-controlled major psycho-affective disorder, inability to comply with complex medical regimen, documented history of non-compliance with medical care or treatment plans.

When services are not covered:
Lung transplantation is **not covered** when the patient has any one of the absolute contraindications listed below:

General contraindications

- Active drug or alcohol abuse, or tobacco use within the last 6 months
- Previous bilateral pleurodesis (increased risk of bleeding)
- Obesity (over 20-30% ideal body weight) at time of transplant
- Cachexia (under 70% of ideal body weight) at time of transplant

  Note: Using standard Metropolitan Life tables, an acceptable weight range is 70 to 130% of ideal body weight. If outside this range, the transplant candidate should receive nutritional counseling. Re-evaluation for transplantation may resume once weight is within range.

- Contraindication to immunosuppressive drugs
- Multiple uncorrectable congenital abnormalities that significantly affect quality and duration of life (such as anencephaly or other severe congenital anomalies)
- Progressive neuromuscular disease.

Contraindications relating to heart and physical

- 6-minute walk test results under 100 feet, since patients this debilitated may experience poor outcomes post transplant
- 6-minute walk test results over 1500 feet, since patients who have this much functional ability may not be appropriate for transplantation

Note: The 6-minute walk test is a valid method for assessing functional capacity for lung transplantation. For standardized 6-minute walk tests, patients should be able to walk 100 to 1500 feet. Those unable to walk 100 feet in 6 minutes warrant careful scrutiny of other parameters to assess appropriateness for transplant, since this degree of disability is a probable predictor of negative post-transplant outcome. Those able to walk over 1500 feet should be carefully reviewed as to their appropriateness for transplant, in light of their functional capacity.

- Neuromuscular weakness causing patient to be wheel-chair bound or unable to ambulate
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Contraindications related to

- HIV positive with or without AIDS
- Hepatitis D: positive blood test
- Active TB infection (unless adequately treated)
- Pan-resistant Burkholderia cepacia in patients with cystic fibrosis
- Bacterial sepsis
- Hepatitis B antigen positivity
- Hepatitis B: DNA positive
- Hepatitis C with biopsy-proven histologic evidence of liver disease

Contraindications related to other diseases

- Current cancer*:* active malignancy within the past 2 years with exception of basal cell and squamous cell carcinoma of skin
- Cancer that, based upon type, and duration of disease-free survival to date, has a significant likelihood of recurring
- Bone marrow failure (any cell line)
- Severe congenital immunodeficiency
- Significant or advanced other disease including: (see individual consideration section)
  - Hepatic dysfunction, including cirrhosis and chronic liver disease
  - Renal dysfunction (creatinine over 1.5 or clearance less than 50 ml/min or less than 35 ml/min for pulmonary hypertension patients) because of the impact of immunosuppressive drugs on renal function.
- Other systemic disease that impairs function or duration of life
- Cerebral dysfunction, such as severe impairments which affect quality of life and ability to comply with transplant regimen
- Behavioral or psychiatric disorder considered likely to compromise adherence with strict medical regimen and follow-up after transplant, including physical rehabilitation

Products to which this policy applies:

- ⊕ Commercial Plan (Direct and Select Plans)
- ⊕ The Independent Plan
- ⊕ Fallon Flex
- ⊕ Major Medical
- ∅ Medicare Plan – refer to CMS for policy and criteria.

References

1. National Institutes of Health selection criteria for lung transplantation, by Handelsman, 1991.
2. Exclusionary criteria published in the Federal Register, Volume 60, Number 22, Feb.2, 1995.
3. United Network for Organ Sharing (UNOS) Criteria, published 8/13/96. The generally accepted maximal age limits are 65 for SLT, 60 years for Bilateral Single Lung, and 55 for HLTxp.
4. American Society of Transplant Surgeons (ASTP) Consensus Conference, sponsored by the NIH and ASTP, May 1997 listing criteria.

5. *Pediatric Lung Transplantation, Indications and Contraindications* by Kurland G, Seminars in Thoracic and CV Surgery, Vol 8. No 3 (July) 1996;277-85.
6. 1998 Joint statement of the American Society for Transplant Physicians, American Thoracic Society, European Respiratory Society, International Society for Heart and Lung Transplantation. See also the international guidelines for the selection of lung transplant candidates: Am J Respir Crit Care Med Vol 158.pp 335-339, 1998; www.atsjournals.org

Approved by:	*Signature on file*	*6/25/2003*
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