Lung and Lobar Lung Transplant

Description

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

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, α₁-antitrypsin deficiency, and idiopathic pulmonary arterial hypertension.

Before consideration for transplant, patients 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 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 (generally friends or family members) in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants.
Since 2005, potential recipients have been ranked according to the Lung Allocation Score. 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 Lung Allocation Score takes into consideration the patient's disease and clinical parameters. In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 years 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.

**OBJECTIVE**

The objectives of this evidence review are to determine whether lung or a lobar lung transplant in individuals with end-stage pulmonary disease and whether lung or a lobar retransplant in individuals with prior lung or lobar transplant improve the net health outcome.

**POLICY STATEMENT**

Lung transplantation may be considered medically necessary for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy (see Policy Guidelines).

A lobar lung transplant from a living or deceased donor may be considered medically necessary for carefully selected patients with end-stage pulmonary disease (see Policy Guidelines).

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.

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

**POLICY GUIDELINES**

### 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.

\(^a\) Some patients may be candidates for combined heart and lung transplantation (see evidence review 7.03.08).

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Lung transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration 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. Lung transplants are included in these regulations.

RATIONALE

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 patients receiving lung transplantation (>50000) found relatively high patient survival rates, especially among those who survived the first year post-transplant. 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 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 is 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 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. 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 patients who meet criteria for initial lung transplantation. Given the exceedingly poor survival prognosis without retransplantation of patients who have exhausted other treatments, the evidence of a moderate level of post-transplant survival may be considered sufficient in this patient population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Society for Heart and Lung Transplantation

Initial Transplant

The International Society for Heart and Lung Transplantation (2006) published consensus-based guidelines on the selection of lung transplant candidates. The guidelines stated that:

"Lung transplantation is now a generally accepted therapy for the management of a wide range of severe lung disorders, with evidence supporting the quality of life and survival benefit for lung transplant recipients. However, the number of donor organs available remains far fewer than the number of patients with end-stage lung disease who might potentially benefit from the procedure. It is of primary importance, therefore, to optimize the use of this resource, such that the selection of patients who receive a transplant represents those with realistic prospects of favorable long-term outcomes..."

In 2014, these recommendations were updated for pulmonary vascular disease. The Society recommended including a transplant list for patients with New York Heart Association class III or IV disease, despite three months or more of combination therapy. Additional clinical indications included a cardiac index of less than 2 L/min/m\(^2\), a mean right atrial pressure of greater than 15 mm Hg, and a 6-minute walk distance of fewer than 350 meters. Also, recommended for transplant listing were significant hemoptysis, pericardial effusion, or signs of progressive right heart failure. Other common indications for lung transplant include interstitial lung disease, idiopathic pulmonary fibrosis, cystic fibrosis, and chronic obstructive pulmonary disease.

Retransplant

Lung retransplantation was addressed briefly, with the consensus statement noting that "criteria for candidate selection for lung retransplantation generally mirror the criteria used for selection for initial lung transplantation."

American Thoracic Society et al

Evidence-based recommendations from the American Thoracic Society and 3 international cardiac societies were published in 2011. For appropriately selected patients with idiopathic pulmonary fibrosis, the group et al recommended lung transplantation (strong recommendation, low-quality evidence)

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Lung transplantation is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. 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.
REFERENCES


**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

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<tr>
<td>March 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Policy statement added indicating lung or lobar lung re-transplantation may be medically necessary. Policy statement added that lung or lobar lung transplantation is considered investigational in all other situations. References updated.</td>
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<td>March 2015</td>
<td>Replace policy</td>
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<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 22, 2017; references 2-3, 9, and 17 added. Conditions for covered indications moved to Policy Guidelines.</td>
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<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 21, 2018; references 2, 18, 20-21, and 26-28 added. Policy statement unchanged.</td>
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<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2019; no references added. Policy statements unchanged.</td>
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