Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a lung or a lobar lung may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
### Transplant | Medical Necessity
--- | ---
Lung transplant | 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 Related Information below).

Lobar lung transplant | 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 Related Information below).

Lung or lobar lung retransplantation | 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.

### Transplant | Investigational
--- | ---
Lung or lobar lung transplant | Lung or lobar lung transplantation is considered investigational in all other situations not outlined above.

HCV (hepatitis C) viremic solid organs | The transplantation of HCV-viremic solid organs (kidney, lung, heart, liver, small bowel, pancreas) to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational.

### Documentation Requirements
The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical documenting the patient has irreversible, progressively disabling, end-stage pulmonary disease that has been unresponsive to maximum medical therapy. Please note the medical therapy trialed and failed. Please specify if request is for lung, lobar lung or retransplantation.
### Code | Description
--- | ---
**CPT**
32851 | Lung transplant, single; without cardiopulmonary bypass
32852 | Lung transplant, single; with cardiopulmonary bypass
32853 | Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854 | Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
**HCPCS**
S2060 | Lobar lung transplantation
S2152 | Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition

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### Related Information

**Lung-Specific Guidelines**

Bilateral lung transplantation is typically required when chronic lung infection and disease is present (ie, 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.

### 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*; or
• Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.

*Some patients may be candidates for combined heart and lung transplantation (see Related Policies).

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

**Benefit Application**

See member’s plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.

**Evidence Review**

**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.
Background

End-stage lung disease may derive from different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD), 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.

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 (>50,000) found relatively high patient survival rates, especially among those 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 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 posttransplant 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.

For individuals who are HCV non-viremic who have end-stage pulmonary disease and are candidates for lung transplant the evidence for the use of HCV viremic donor organs as an alternative to continuing appropriate medical treatment and remaining on the transplant waitlist consists of preliminary results of a single open-label nonrandomized trial of 36 HCV viremic lung transplants treated with 4 weeks of pangenotypic direct-acting antiviral agents (DAAs). The primary outcomes were sustained virologic response (SVR) and graft function and survival. SVR at 12 weeks and graft survival at 6 months was available for 28 participants and both rates were 100%. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT00905463</td>
<td>Analysis of Prognosis and Patients Reported Outcomes in Lung Transplant Candidates</td>
<td>272</td>
<td>Mar 2022</td>
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<tr>
<td>NCT00177918</td>
<td>Prospective Evaluations of Infectious Complication in Lung Transplant Recipients</td>
<td>600</td>
<td>Dec 2025</td>
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<td>NCT03523871</td>
<td>A Single-center Pilot Study of the Use of Hepatitis C Positive Donors for Hepatitis C Negative Lung Transplant Recipients With Post-transplant Treatment With Mavyret</td>
<td>20</td>
<td>Jun 2020</td>
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<tr>
<td>NCT03625687</td>
<td>Pan-genotypic Direct Acting Antiviral Therapy in Donor HCV-positive to Recipient HCV-negative Lung Transplant</td>
<td>25</td>
<td>Apr 2021</td>
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<tr>
<td>NCT03086044</td>
<td>Transplanting Thoracic Organs From Hepatitis C Positive Donors to Hepatitis C Uninfected Recipients</td>
<td>100</td>
<td>Dec 2021</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
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<tr>
<td>NCT03112044</td>
<td>Lung Transplantation Using Hepatitis C Positive Donors to Hepatitis C Negative Recipients: A Pilot StudyDonor lungs will be subjected to normothermic Ex vivo Lung Perfusion (EVLP) for 6 hours for organ assessment and reduction of viral load prior to transplantation.</td>
<td>20</td>
<td>Dec 2018</td>
</tr>
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NCT: national clinical trial.

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/m², 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 three 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).

**The American Society of Transplantation**

The American Society of Transplantation (2017) convened a consensus conference of experts to address issues related to the transplantation of hepatitis C virus (HCV) viremic solid organs into HCV non-viremic recipients and concluded that the transplantation of organs from HCV viremic donors into HCV-negative recipients should be conducted only under monitored IRB-approved protocols and studies.
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.

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.

References


### History

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<td>11/01/19</td>
<td>New policy, approved October 4, 2019. Content previously addressed in policy 7.03.509. Policy created with literature review through June 2019. Lung and lobar lung transplantation may be considered medically necessary when criteria are met. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14.</td>
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