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.
## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32854</td>
<td>Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
</tr>
<tr>
<td>S2152</td>
<td>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</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## 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

Solid organ transplantation offers a treatment option for patients with different types of end stage organ failure that can be lifesaving or provide significant improvements to a patient’s quality of life.1 Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Lung Transplant

In 2019, 39,719 transplants were performed in the United States procured from almost 11,900 deceased donors and 7,400 living donors.2 Lung transplants were the fourth most common procedure with 2,714 transplants performed from both deceased and living donors in 2019.

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.

Potential recipients who are 12 years of age and older are ranked according to the Lung Allocation Score.3 A score may range between 0 and 100 and incorporates predicted survival after transplantation and predicted survival on the waiting list; the Lung Allocation Score takes into consideration the patient’s disease and clinical parameters. Waiting list incorporates the Lung Allocation Score, geography, and blood type classifications. Children younger than 12 years old receive a priority for lung allocation. Under this system, children younger than 12 years old 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 wait-list 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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00905463</td>
<td>Analysis of Prognosis and Patients Reported Outcomes in Lung Transplant Candidates</td>
<td>272</td>
<td>Mar 2022</td>
</tr>
<tr>
<td>NCT00177918</td>
<td>Prospective Evaluations of Infectious Complication in Lung Transplant Recipients</td>
<td>600</td>
<td>Dec 2025</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

International Society for Heart and Lung Transplantation

Initial Transplant

In 2006, The International Society for Heart and Lung Transplantation 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 patients with 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**

The 2014 guideline update briefly addressed lung retransplantation, with the consensus statement noting that "criteria for candidate selection for lung retransplantation generally mirror the criteria used for selection for initial lung transplantation."29

**American Thoracic Society et al**

Evidence-based recommendations from the American Thoracic Society and three international cardiac societies were published in 2011 for the diagnosis and management of patients with idiopathic fibrosis.30 For appropriately selected patients with idiopathic pulmonary fibrosis, the international guideline panel 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.31 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 (FDA).

The FDA 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 subject to these regulations.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5952, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


Getting Help in Other Languages

This Notice has Important Information. This notice may have important dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Ayi sila a gen Enfòmasyon Enpòtan ladann. Ayi sila a kapab genyen enfòmasyon enpòtan konpiesen aplikaasyon w lam oswa konpiesen kovètii asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan ayi sila a. Ou ka gen pou prin kék aksyon avan seten dat limit pou ka kente kovètii asirans sante w la oswa pou yo ka ede w akèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pa ale a, san ou pa gen pou pey ey peou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaa ket naglao iti Napateg nga Impormasion. Daytoy a pakdaa mabilan nga adda ket naglao iti napateg nga impormasion maipanggep iti aplikaasyonyo wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabilan dagiti importante a petaa iti daytoy a pakdaa. Mabilan nga adda rumbeng nga aramidenyo nga addang sakyab dagiti partikular a naletting nga addaw tapno mapagtalinadeyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodayo a pagasasao nga awan ti bayadanyo. Tumawig ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
This notification may contain important information. This notification may contain important information. Este aviso puede contener información importante. La notificación puede contener información importante. Si esta notificación contiene información importante, por favor consulte con su aseguradora de salud Blue Cross. Si esta notificación contiene información importante, por favor consulte con su aseguradora de salud Premera Blue Cross. Este aviso puede contener información importante. Pode conter informações importantes.

CN (Chinese): 本通知中包含重要信息。请与Premera Blue Cross或提供的服务提供商联系以获取更多信息。这可能包含重要信息。

ES (Spanish): Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Este aviso puede que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).


GR (Greek): Αυτή η ενημέρωση μπορεί να περιέχει σημαντικές πληροφορίες. Παρακαλούμε να επικοινωνήσετε με την Premera Blue Cross για περαιτέρω πληροφορίες.

IT (Italian): Questa notifica potrebbe contenere informazioni importanti. Si prega di contattare Premera Blue Cross per ulteriori informazioni.


TR (Turkish): Bu belge önemli bilgi içerebilir. Eğer bu bilgi önemlidir, Premera Blue Cross’e başvurun.